CANADA

REGULATIONS

UNDER THE

FOOD AND DRUGS ACT

MADE BY

ORDER IN COUNCIL

16th August, 1934

DEPARTMENT OF PENSIONS AND NATIONAL HEALTH
OTTAWA

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(123/1852)

CERTIFIED to be a true copy of a Minute of a Meeting of the Treasury Board, approved by His Excellency the Governor General in Council, on the 16th August, 1934.

PENSIONS AND NATIONAL HEALTH

THE Board recommend that the Regulations under the Food and Drugs Act made by Orders in Council of the 6th February, 1928 (P.C. 197), 28th November, 1929 (P.C. 2313), 3rd July, 1930 (P.C. 1469), 23rd August, 1930 (P.C. 2008), 11th March, 1931 (P.C. 534), 17th June, 1931 (P.C. 1429), 11th August, 1931 (P.C. 1860), and 19th March, 1934 (P.C. 188), be cancelled and the attached substituted therefor.

(Sgd.) E. J. LEMAIRE,
Clerk of the Privy Council.

The Honourable
the Minister of Pensions
and National Health.

REGULATIONS UNDER THE FOOD AND DRUGS ACT

DIVISION I

I. Section 3 (*b*).—LABELLING

1. "The Label" may be an integral part of the package.

(*a*) Food and Drug products shall be designated by their common names in one or other or both of the official languages.

2. The common name of the article above referred to shall appear on the main panel of the main label. The name and address of the manufacturer, or that of the person or firm for whom the article is manufactured, shall appear clearly and conspicuously.

3. When the article is a compound, a mixture, a substitute, an imitation or is artificial, these words shall appear on the main panel of the main label in type of the same size and visibility as the common name used, and as part of the same.

4. The term "Blend" shall be applied only to a combination of similar substances.

Example: A combination of Java, Mocha and Brazilian coffees is a Blend.

5. A combination of coffee with chicory or roasted grain is not a Blend, but a Mixture or Compound. The terms "Compound" and "Mixture" are interchangeable.

6. In the case of Compounds or Mixtures, when the name of an ingredient is used in designating the article, such ingredient shall be present in amount at least equal to 51 per cent by weight of the whole.

Example: A coffee Compound or Mixture shall contain at least 51 per cent of actual coffee.

7. In labelling any food product for which a distinctive name is used, the list of ingredients shall be stated clearly and conspicuously.

8. (*a*) A Distinctive Name is a trade, arbitrary or fancy name which clearly distinguishes a food product, compound or mixture from any other food product, compound or mixture.

(*b*) A distinctive name shall give no false indication of origin, character, or place of manufacture, nor lead the purchaser to suppose that it is any other food product.

9. When colour or preservative which requires declaration or artificial flavour is added, these shall be declared on the main panel of the main label in easily legible type.

10. If any substitute for sugar is used, the presence of such substitute shall be declared on the main panel of the main label in easily legible type.

11. Except as hereinafter provided, upon the label of any drug whether upon the inner container or upon the outside of the package, and upon both if an outer wrapper or carton is used, containing the article, there shall be printed in easily legible type with distinct visibility a complete list of the medicinal ingredients contained therein, employing for this purpose the names by which these ingredients are commonly known, and, unless it be solely for veterinary purposes, with a statement of the quantitative proportionate content of any ingredient named in the Schedule to the Proprietary or Patent Medicine Act, with recommended dosage of the preparation within the limits prescribed by the Advisory Board appointed thereunder. This shall not be required if standards for the drug are prescribed by Section 6 of the Food and Drugs Act, or if it is sold under a registration number assigned under the authority of the Proprietary or Patent Medicine Act.

12. Any preparation of coal tar derivatives purporting to be of value as a disinfectant or germicide, shall bear upon the label a statement of the phenol co-efficient as determined by the method of The Hygienic Laboratory, referable either to *B. typhosus* or to *Mic. aureus* as test micro-organisms.

II. Section 3 (*c*).—General Instructions to Inspectors

1. Twenty-five inspectoral districts shall be defined.

2. Except when acting under special instructions, the Local Inspector shall limit his activities to the particular district for which he is appointed. He shall make himself familiar with the routes of travel therein.

3. The Senior Inspectors shall not be limited as to territory, and may be required to operate in any district. In such case, the Local Inspector shall give every assistance possible.

4. Every Senior Inspector shall also be regarded as a Local Inspector for the district in which he resides. He shall operate outside of this district in case of emergency, or on instructions from the Department.

5. Every Inspector shall make himself thoroughly familiar with the Food and Drugs Act, the Proprietary or Patent Medicine Act, and all revisions or amendments of these, as well as all regulations established under them.

6. As far as opportunity permits, Inspectors shall familiarize themselves with the conditions under which articles covered by these various Acts are manufactured, imported and sold at retail in their several districts. They are furnished with business cards which they shall leave with persons interested in, or likely to be interested in their work; and generally to secure, as far as may be, the sympathetic co-operation of dealers, wherever they go.

7. It shall be the duty of the Inspector to investigate as fully as may be, every complaint made to him. This shall be done by correspondence, and wherever necessary, by personal investigation. Whenever the Inspector's judgment leads him to believe that cases are well founded and of sufficient importance, he shall communicate full details to the Senior Inspector, and receive further instructions as to procedure.

NOTE.—For purposes of Section 7, the Inspectors from districts shall communicate as follows:—

From Districts 2, 3 and 4—To: Mr. R. J. Waugh, Post Office Box 206, Halifax, N.S.

From Districts 5, 6 and 7—To: Mr. J. St. Onge, 170 Place d'Youville, Montreal, P.Q.

From Districts 10 and 15—To: Mr. T. L. Leckie, Sussex and John Streets, Ottawa, Ont.

From Districts 12, 13 and 14—To: Mr. W. E. Wilson, 59 Victoria Street, Toronto, Ont.

From Districts 16, 18, 19 and 20—To: Mr. Geo. W. Thompson, Cor. Magnus and Main, Winnipeg, Man.

From Districts 21, 22, 23 and 25—To: Mr. J. Cullen, 402 Pender Street W., Vancouver, B.C.

8. Inspectors will, from time to time, receive instructions for systematic collection of named articles. In all such cases, they shall exercise judgment in their work, and endeavour to secure samples representing the lowest classes of such goods on the market, as these are the products most likely to require action.

In addition to the purchase of samples as above referred to, the Inspector is authorized to procure and submit for analysis any samples of Food or Drugs, which he may have reason to believe are in any respect suspicious, or in any way offered for sale in contravention of the Acts administered by this Department.

NOTE:—Samples for analysis shall be sent as follows:

To Ottawa, from Districts 9, 10, 12, 13, 14, 15.
To Halifax, from Districts 1, 2, 3, 4.
To Montreal, from Districts 5, 6, 7, 8.
To Toronto, from District 11.
To Winnipeg, from Districts 16, 17, 18, 19, 20.
To Vancouver, from Districts 21, 22, 23, 24, 25.

9. It shall be the Inspector's duty to lay information in all cases of reported violation of the Acts administered by this Department. He shall be furnished, as far as possible, with the names of local solicitors who may be called in to assist him when cases are defended or otherwise complicated. In all such cases he shall give the Department Solicitor every assistance possible.

10. In the event of fines and costs, unless remittance is made by the Court, the Inspector shall receive and forward such, the instrument in every case made payable to the Receiver General of Canada.

11. The Inspector shall keep in touch with the Local Customs Officers, and shall detain, for examination before release, any importations of such articles as are covered by the Acts and regarding which he has reason to believe that the goods are fraudulent, or are likely to be used for purposes of fraud.

In all such cases he shall obtain samples and forward at once for analysis, with full information regarding them.

12. The Inspector shall keep in touch with the local branch of the Retail Merchants' Association and other organizations of this kind.

13. Our Bulletins, etc., will be supplied to each Inspector, and he shall see that they are distributed to interested parties.

14. The Proprietary or Patent Medicine Act provides that registered articles can be sold legally by manufacturers only when the license fee for the year is paid. A list of registered articles upon which the license fee has not been paid, will be furnished to every Inspector, and the Inspector shall take action as instructed.

III. Section 3 (*a*).—Net Contents Tolerances

The following tolerances and variations from the quantity of the contents marked on the package shall be allowed under Section 7 (*f*) except in cases where it is stated in terms of minimum weight, measure or count.

1. Discrepancies due exclusively to errors in weighing, measuring or counting which occur in packing conducted in compliance with good commercial practice.

2. Discrepancies due exclusively to differences in the capacity of bottles and similar containers resulting solely from unavoidable difficulties in manufacturing such bottles or containers so as to be of uniform capacity: Provided that no greater tolerance shall be allowed in case of bottles or similar containers which, because of their design, cannot be made of approximate uniform capacity than is allowed in case of bottles or similar containers which can be manufactured so as to be of approximate uniform capacity.

3. Discrepancies in weight or measure, due exclusively to differences in atmospheric conditions in various places, and which unavoidably result from the ordinary and customary exposure of the packages to evaporation or to the absorption of water.

Discrepancies under classes (1) and (2) of this paragraph shall be as often above as below the marked quantity. The reasonableness of discrepancies under class (3) of this paragraph shall be determined on the facts in each case.

IV. Section 3 (*d*).—Tariff of Fees for Analysis

Baking Powders		
Determination of gas production—		
Single sample		$ 5 00
More than one sample each		3 00
Complete analysis	$ 5 00 to	10 00
Beer, Wine, Distilled Liquors, Etc.		
Alcohol determination		5 00
Complete analysis	5 00 to	25 00
Butter and Cheese		
Determination of Water, Salt and Fat—		
Single sample		3 00
Two samples at one time		5 00
More than two samples each		2 00
Examination for foreign fats, per sample		5 00
Coffee and Tea		
Examination as to genuineness	3 00 to	5 00
Confectionery		
Confectionery	2 00 to	10 00
Edible Oils		
Edible Oils	2 00 to	10 00
Flour		
Examination for bleaching		5 00
Honey		
Examination as to genuineness	5 00 to	10 00
Jams		
Examination as to genuineness	5 00 to	10 00
Lard		
Examination for foreign fats		5 00
Milk		
Determination of Specific Gravity, Water, Fat and Non-fat Solids—		
Single sample		5 00
Two samples at same time		8 00
Bacterial Count in addition to above	Double the fee named	
Spices		
Ash, water soluble ash and microscopical identification of starch		5 00

Miscellaneous

Ten dollars shall be accepted as the cost of procuring and analysing any sample found to violate the provisions of this Act.

For analyses made for other departments of the Government service for legal purposes, the flat rate per sample shall be five dollars.

In all cases not covered by the above schedule, a fee of two dollars shall be charged for each separate determination required.

V. Section 3 (h)—Division of Samples

Unless otherwise instructed, the following list shall serve as a guide to inspectors in procuring samples. When three packages are purchased as a sample, each package, when officially sealed, shall constitute a portion thereof.

Baking Powder: When in packages, three of the smallest, otherwise one-half pound to be placed in air-tight containers.

Beer and Malt Liquors: Three bottles or three pints.

Bread: Fancy bread, rolls, etc., three pounds or three loaves.

Butter: One pound.

Cheese: One pound.

Cocoa and Chocolate: One pound; if packaged, three smallest sized packages.

Coffee: One pound.

Cream of Tartar: Same as Baking Powder.

Drugs: Special instruction in each case.

Farinaceous Foods: Infants' and Invalids' Foods. In tins either three of the smallest size or one pound.

Flour: One and a half pound.

Lard: Same as Butter.

Lime and Lemon Juice: One quart or three bottles.

Milk: Three pint bottles, or three quart bottles.

Mustard and Spices: Same as Cocoa and Chocolate.

Preserves and other Canned, Packaged or Potted Goods: Three small tins, packages or pots.

Sugar: One pound (if for colour, 12 pounds).

Tea: One pound.

Vinegar: One quart or 3 bottles.

Wines and Alcoholic Liquors: Three bottles or three pints.

When a printed wrapper or label encloses or is attached to the original package, this shall be attached to the analyst's portion of the sample.

VI. Section 3 (h)—Inspection Districts

No. *Name of District*

1. Nova Scotia—
   The Province except Cape Breton Island.
2. Cape Breton Island—
   The Island.
3. Prince Edward Island—
   The Island.
4. New Brunswick.
   The Province.
5. Quebec—
   The City of Quebec and the Province east of, and including the counties of Quebec, Levis and Dorchester.
6. Eastern Townships—
   The Province of Quebec, south of the St. Lawrence River, between Quebec and Montreal Districts.
7. Three Rivers—
   The Province of Quebec, north of the St. Lawrence River, between Quebec and Montreal Districts.
8. Montreal—
   The City and Island, also the counties of Laval, Terrebonne, Argenteuil, Vaudreuil, Two Mountains, Soulanges, Beauharnois, Huntingdon, Châteauguay, Laprairie, Napierville, St. Jean, Chambly and Verchères.
9. Ottawa—
   West of Montreal District, as far as a line joining Gananoque and Pembroke, and north of the St. Lawrence River.
10. Belleville—
    The Province of Ontario, between Gananoque and Oshawa, and south of Algonquin Park.
11. Toronto—
    The City of Toronto and the counties of York, Ontario, Simcoe, Muskoka and Parry Sound.

No. *Name of District*

12. Hamilton—
The City of Hamilton and the counties of Peel, Halton, Wentworth, Lincoln, Haldimand, Welland and Brant.

13. London—
The City of London and the counties of Middlesex, Lambton, Essex, Kent, Elgin, Oxford and Norfolk.

14. Guelph—
The City of Guelph and the counties of Wellington, Waterloo, Perth, Huron, Bruce, Grey and Dufferin.

15. Northern Ontario—
The Sudbury District, Algoma, Nipissing and Temiskaming.

16. Fort William—
Port Arthur, Fort William, District of Thunder Bay, Kenora, and Rainy River.

17. Winnipeg—
The City of Winnipeg and the Province of Manitoba east of, and including Portage la Prairie.

18. Brandon—
The City of Brandon and the Province of Manitoba west of Winnipeg District.

19. Regina—
The City of Regina and the Province of Saskatchewan south of and including Yorkton.

20. Saskatoon—
The City of Saskatoon and the Province of Saskatchewan north of Regina District.

21. Calgary—
The City of Calgary and the Province of Alberta south of Didsbury.

22. Edmonton—
The city of Edmonton and the Province of Alberta north of Calgary District.

23. Rocky Mountain—
The Province of British Columbia, east of and including Kamloops.

No.	*Name of District*
24.	Vancouver—The City of Vancouver and the mainland of British Columbia west of Rocky Mountain District.
25.	Victoria— The City of Victoria and Vancouver Island.

District No.	Inspector
1.	R. J. Waugh (Sen.)— (P.O. Box 206), Golden Building, Sackville Street, Halifax, N.S.
2 and 3.	Murray F. Johnstone— National Revenue Building, Sydney, C.B.
4.	R. R. Kimball— 59 Princess Street, Saint John, N.B.
5.	J. O'Donnell— (P.O. Box 362), Post Office Building, Quebec, P.Q.
6.	R. Alexander— Room 15, Gregoire Building, Wellington St. N., Sherbrooke, P.Q.
7.	U. L. Gingras— Post Office Building, Three Rivers, P.Q.
8.	J. St. Onge (Sen.)— 170 Place d'Youville, Montreal, P.Q.
8.	B. Fontaine— 170 Place d'Youville, Montreal, P.Q.
9.	T. L. Leckie, (Sen.)— Sussex and John Streets, Ottawa, Ont.
10.	J. E. Dixon— Bank of Commerce Chambers, 235 Front Street, Belleville, Ont.

District No.	Inspector
11.	W. E. Wilson (Sen.)— 59 Victoria Street, Toronto, Ont.
11.	J. D. Macdonald— 59 Victoria Street, Toronto, Ont.
12.	A. W. Cooke— (P. O. Box 222), Post Office Building, Hamilton, Ont.
13.	E. B. Thurlow— (P.O. Box 538), Customs Building, London, Ont.
14.	C. E. Abrams, (P.O. Box 33), Post Office Building, Guelph, Ont.
15.	W. R. Moon— Post Office Building, Sudbury, Ont.
16.	Thos. Stewart— Customs Building, Fort William, Ont.
17.	Geo. W. Thompson (Sen.)— Cor. Magnus and Main, Winnipeg, Man.
18.	E. L. Hughes— Brandon, Man .
19 and 20.	F. A. Kirby— Post Office Building, Regina, Sask.
21.	H. G. Hibbs— (P.O. Box 105), Customs Building, Calgary, Alta.
22.	J. L. Hollinshead— 304 Blowey Henry Building, Edmonton, Alta.

District No.	Inspector
23.	A. S. Horswill— (P.O. Box 578), Post Office Building, Nelson, B.C.
24.	J. Cullen (Sen.)— 506-516 B.C. Mining Building, 402 Pender Street W., Vancouver, B.C.
25.	W. S. Ritchie— Room 402, Post Office Building, Victoria, B.C.

VII. Section 3 (f).—Disposal of Imports Refused Entry

1. A certificate of analysis (as per F. & D. No. 17) shall be sent to the Collector of Customs refusing entry under Section 10 (3) of the Act.

2. The importer, where known, shall also receive due notice of the refusal of entry.

3. If the goods are unclaimed, or refused by the importer they shall be exported within three months of the date of refusal of entry, or they shall (ipso facto) be forfeited to the Crown, and may be disposed of as the Minister directs.

4. Goods may be released after relabelling to comply with the law, or after certain conditions are complied with, which conditions shall be given in writing in each case. If the release is conditional upon the destruction of the rejects, or some portion of the shipment, the balance of the goods shall be held until this is done. If the goods are not properly conditioned within the period allowed, they shall be exported or destroyed.

5. The privilege of relabelling, cleaning or similarly renovating may be refused, when the importer or exporter has been informed of violations in previous shipments.

6. When importations are shipped to another port for reconditioning or exportation the goods shall be shipped under Customs carrier's manifest as a shipment in bond.

VIII. Section 3 (*g*).—Dominion Analysts

The following members of the technical staff appointed to the services of the Department of Pensions and National Health are designated as Dominion Analysts:—

F. E. Artlett
C. W. Chapman
F. C. Collier
A. Papineau Couture
A. L. Davidson
W. A. Davidson
J. Dick
E. L. C. Forster
C. C. Forward
J. Gibbard
N. MacL. Harris
H. R. L. Hart
W. H. Hill
L. E. Johnson
V. Kitto
C. A. Morrell
H. O. Tomlinson
A. Valin
H. A. Watson
R. D. Whitmore
E. F. Whyte

FOOD STANDARDS

Sections 3 (*a*) and 3 (*b*)

I. Baking Powder and Baking Powder Materials

1. Baking Powder shall be essentially a mixture of sodium bicarbonate with an acid either free or in combination as an acid salt, together with starch or other neutral material, intended to be used as a leavener in baking, the leavening agent being the carbon dioxide liberated by interaction of the acid component with the sodium bicarbonate under the conditions of baking.

2. The acid materials employed in the manufacture of baking powders shall be in themselves harmless to health, and the compounds resulting from their interaction with sodium bicarbonate shall also be harmless to health.

3. Baking Powder shall be capable of yielding ten (10) per cent of its weight of carbon dioxide, when tested by the method prescribed in Section XVIII.

4. Cream of Tartar shall be essentially an acid salt obtained from the crude tartar deposited during the fermentation of grape juice. It shall contain at least eighty-eight (88) per cent of potassium bitartrate.

5. Pure Cream of Tartar shall contain not less than ninety-nine (99) per cent of potassium bitartrate.

6. The proportion of Arsenic (Arsenious Oxide, As_2O_3) in the following articles shall not exceed the limitation here specified in each case.

	Parts per million
Tartaric Acid	1
Cream of Tartar	2
Sodium Bicarbonate	2
Calcium Phosphate	5
Sodium Phosphate	5
Baking Powder	2

II.—Beverages

A. Fruit Juices: Fresh Sweet and Fermented

1. *Fruit Juices*

1. Fruit Juices shall be the clean unfermented liquid products obtained by the first pressing of fresh, ripe fruit (see definition of fruit, Section VII) and shall correspond in name to the fruits from which they shall be obtained, and shall contain not more than two (2) per cent of alcohol by volume.

2. Apple Juice, Apple Must, Sweet Cider, Cider, whether the fresh juice or a dilution of a juice concentrate obtained from apple, the fruit of *Pyrus malus,* shall have a specific gravity (20° C) not less than 1·0415 nor greater than 1·0690; and shall contain in one hundred (100) cubic centimetres (20°C) not less than six (6) grams, and not more than twenty (20) grams of total sugars in terms of reducing sugars, not less than twenty-four (24) centigrams nor more than sixty (60) centigrams of apple ash which shall contain not less than fifty (50) per cent of potassium carbonate.

3. Grape Juice, Grape Must, shall be the juice obtained from grapes (*Vitis* species) shall have a specific gravity (20° C) not less than 1·0400 and not exceeding 1·1240; and shall contain in one hundred (100) cubic centimetres (20° C) not less than seven (7) grams nor more than twenty-eight (28) grams of total sugars in terms of reducing sugars, not less than twenty (20) centigrams and not more than fifty-five (55) centigrams of grape ash, and not less than fifteen (15) milligrams nor more than seventy (70) milligrams of phosphoric acid (P_2O_5).

4. Lemon Juice shall be the juice obtained from lemons, the fruit of *Citrus limonum* Risso, shall have a specific gravity (20° C) not less than 1·030 and not greater than 1·040; and shall contain not less than ten (10) per cent of solids and not less than seven (7) per cent of citric acid.

5. Lime Juice, Lime Fruit Juice, shall be the expressed juice of the ripe fruit of Citrus (various species) and shall have a specific gravity (20° C) not less than 1·030 and not greater than 1·040, and shall contain not less than eight (8) per cent of solids and not less than seven (7) per cent of citric acid. Its optical activity (rotatory power to polarized light) shall lie between the limits of 0·5° and 1·5° of the Soleil-Ventzke scale when observed in a column of 200 mm. length at 20° C.

6. Pear Juice, Pear Must, Sweet Perry, shall be the juice obtained from pears, the fruit of *Pyrus communis* or *P. sinensis*.

2. *Sterilized Fruit Juices*

1. Sterilized Fruit Juices shall be the products obtained by heating fresh fruit juices sufficiently to kill all the organisms present, and shall correspond in name to the fruits from which they shall be obtained.

3. *Concentrated Fruit Juices*

1. Concentrated Fruit Juices shall be clean, sound fruit juices from which a considerable portion of the water has been evaporated, and shall correspond in name to the fruits from which they shall be obtained.

4. *Sweet Fruit Juices, Sweetened Fruit Juices, Fruit Syrups*

1. Sweet Fruit Juices, Sweetened Fruit Juices, Fruit Syrups, shall be the products obtained by adding sugar (sucrose) to fresh fruit juices and shall correspond in name to the fruits from which they shall be obtained.

2. Sterilized Fruit Syrups shall be the products obtained by the addition of sugar (sucrose) to fresh fruit juices, and heating them sufficiently to kill all the organisms present, and shall correspond in name to the fruits from which they shall be obtained.

5. *Fermented Fruit Juices*

1. Wine shall be the product of the normal alcoholic fermentation of the juice of sound ripe grapes, neat or variously modified, and followed by proper cellar treatment.

2. All beverages sold or offered for sale as wine shall be distinctly labelled to show the place of their production; and shall meet the requirements for wine, established by law in the place of their production.

3. Wine made in any part of Canada shall be labelled in such a way as to show the locality in which it has been produced.

4. Hard Cider shall be the product made by the normal alcoholic fermentation of apple juice, and the usual cellar treatment, and shall contain not more than seven (7) per cent by volume of alcohol and in one hundred (100) cubic centimetres (20° C) of the cider, not less than two (2) grams nor more than twelve (12) grams of solids, nor more than eight (8) grams sugar in terms of reducing sugars and not less than twenty (20) centigrams nor more than forty (40) centigrams of cider ash.

5. Sparkling Cider, Champagne Cider, shall be cider impregnated with carbon dioxide under pressure, with or without the addition of sugar liquor, and shall contain in one hundred (100) cubic centimetres (20° C) not less than twenty (20) centigrams of cider ash.

B. Malt Liquors and Malt Beverages

1. Malt Liquor shall be a beverage made by the alcoholic fermentation of an infusion in potable water, of malted grain and hops.

2. Ale or Beer shall be a beverage made by the alcoholic fermentation of an infusion in potable water, of malt and hops with or without other starchy and saccharine matter.

2*a*. Unless the label indicates otherwise, beer shall contain not less than three and five-tenths (3·5) per cent of absolute alcohol by volume.

2*b*. Beer containing not less than three and five-tenths (3·5) per cent of absolute alcohol by volume, if heated or pasteurized, shall contain in one hundred (100) cubic centimetres (20° C), not less than three and five-tenths (3·5) grams of extractives and not less than eleven hundredths (0·11) gram of ash, chiefly potassium phosphate.

C. Spirituous Liquors

1. Crude Alcohol or Distilled Spirits shall be the distillate obtained from a fermented mash of cereals, molasses, sugars, fruits, or other fermentable substances, and shall contain all the volatile flavours, essential oils, and other substances derived directly from the materials used, and the higher alcohols, ethers, acids and other volatile bodies, congeneric with ethyl alcohol produced during fermentation.

NOTE.—The term alcohol is here restricted to ethyl alcohol.

2. It shall not be held to be a violation of the following definitions and regulations if a spirituous liquor designated by any of the names mentioned under items 3 to 12 inclusive contains a lower percentage of absolute alcohol than the percentage stated as a minimum in the definition, provided that the percentage actually contained be printed legibly and distinctly upon each and every package and label of such spirituous liquor.

3. Alcohol, Cologne Spirits, Neutral Spirits, Velvet Spirit or Silent Spirits, shall be crude alcohol from which all, or practically all of its constituents except ethyl alcohol and water shall be separated, and shall contain not less than ninety-four and two-tenths (94·2) parts by volume of absolute alcohol in one hundred parts by volume.

4. Whisky shall be spirit obtained by distillation from a mash of cereal grains, saccharified by the diastase of malt, and shall contain not less than forty-two and seventy-five hundredths (42·75) per cent of absolute alcohol by volume.

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5. Scotch Whisky shall be whisky made in Scotland, and shall contain not less than forty-two and seventy-five hundredths (42·75) per cent of absolute alcohol by volume.

6. Irish Whisky shall be whisky made in Ireland, and shall contain not less than forty-two and seventy-five hundredths (42·75) per cent of absolute alcohol by volume.

7. Brandy shall be spirit obtained by the distillation of wine, and shall contain not less than forty-two and seventy-five hundredths (42·75) per cent of absolute alcohol by volume.

8. Imitation Brandy, British Brandy, shall be compounded spirit prepared by a rectifier or compounder, by redistilling spirit made from grain, with flavouring ingredients, or by adding flavouring materials to such spirit and shall contain not less thant forty-two and seventy-five hundredths (42·75) per cent of absolute alcohol by volume.

9. Rum shall be potable spirit distilled direct from fermented sugar cane products, and shall contain not less than forty-two and seventy-five hundredths (42·75) per cent of absolute alcohol by volume.

10. Imitation Rum shall be compounded spirit prepared by a rectifier or compounder, by redistilling spirits, with flavouring ingredients, or by adding flavouring materials to such spirits, and shall contain not less than forty-two and seventy-five hundredths (42·75) per cent of absolute alcohol by volume.

11. Gin shall be potable spirit sweetened or unsweetened prepared from grain spirit specially rectified and redistilled with juniper berries and flavouring herbs, and shall contain not less than thirty-seven (37) per cent of absolute alcohol by volume.

12. Imitation Gin shall be compounded spirit, prepared by adding flavouring materials to such spirits, and shall contain not less than thirty-seven (37) per cent of absolute alcohol by volume.

13. Liqueurs, Cordials, etc., shall be compounded spirits, containing sugar and other dissolved matters, and shall be prepared from alcohol or other spirituous liquors by infusion, by distillation or by the use of essences, or other flavourings.

III. Canned Fruits and Vegetables

1. Canned Fruits, Canned Vegetables, shall be the sound products made by sterilizing clean, sound,

properly matured and prepared fresh fruits or vegetables, by means of heat, and keeping the same in suitable, clean containers, closed hermetically or otherwise (see note re containers, under meat, Section IX); and shall conform in name to the particular fruits or vegetables used in their preparation.

2. Any descriptive terms applied to these articles upon the labels or otherwise, shall be consistent with the definitions of such terms as established by Order in Council under the Meat and Canned Foods Act.

3. The use of copper sulphate or other artificial colour for colouring canned peas shall be prohibited.

IV. Colours in Food

1. Food may be coloured with certain harmless colours, provided that the added colour does not conceal damage, nor make the food appear better or of greater value than it really is. (See Section 7 (*d*) of the Food and Drugs Act).

2. The following colours may be added to food. These and no others may be used.

Natural Colours

Caramel, Cochineal, Saffron, Chlorophyll and other innocuous vegetable colour extractives.

Artificial Colours
(*Coal Tar Dyes*)

Number Colour Index of 1924 Society of Dyers and Colourists, Great Britain		Number Schultz and Julius Translated by A. G. Green, MacMillan Co., 1904.
	Red Shades	
184	Amaranth	107
80	Ponceau 3R	56
773	Erythrosine	517
	Orange Shades	
150	Orange 1	85
	Yellow Shades	
10	Naphthol Yellow S	4
640	Tartrazine	94
22	Yellow A.B.	
61	Yellow O.B.	
	Green Shades	
670	Light Green S.F. Yellowish	435
	Blue Shades	
1180	Indigo Carmine Disulphonic Acid	692

The Triphenylmethane dye, only the Disodium salt corresponding to ammonium salt Alphazurine FG, No. 671, Colour Index, Society of Dyers and Colourists, Great Britain (Brilliant Blue FCF, U.S. Dept. Agric.).

The above coal tar dyes must have been manufactured in specially pure form for food purposes, and must not contain Arsenic in excess of ten (10) parts As_2O_3 per million reckoned upon the actual weight of colouring matter, nor heavy metals (iron excepted).

The proportion used must not exceed two grains of dye per pound of food (1 part in 3500).

3. The label on each and every package of food colour shall bear a statement by the manufacturer or by a responsible dealer resident in Canada declaring that the contents meet the requirements of the Food and Drugs Act of Canada.

4. Colouring of the following foods has been allowed without label declaration, with the special limitation noted.

Full Whole Milk Cheese, Ice Cream and Ices, Confectionery (inclusive of Jelly Powders), Butter, Flavouring Extract of Lemon, Smoked Fish.

The following articles may be coloured with caramel only, without declaration of such colouring;

Vinegar (excepting Spirit Vinegar and blends containing Spirit Vinegar), Spirits, non-excisable Fermented Beverages, Summer or so-called Temperance Beverages, Sauces.

5. Colouring shall be prohibited in the following foods:

Meat and Meat Products, Vanilla Extract, Spirit Vinegar and Blended Vinegar containing Spirit Vinegar.

Because of possible injury to health, the use of copper or copper compounds, in colouring fruit and vegetable products shall be prohibited.

6. In all cases except such as are mentioned in paragraphs 4 and 5, above, the presence of artificial colouring must be declared in easily legible type on the main panel of the main label.

V. Edible Vegetable Fats and Oils

Edible Fats, Edible Oils, shall be such glycerides of the fatty acids as are recognized to be whole-

some foods. They shall be dry and sweet in flavour and odour.

1. Olive Oil, Sweet Oil, shall be entirely a product of the fruit of the olive tree. Its specific gravity, at 15·5° C., is not less than 0·9140 nor more than 0·9196; refractive index, at 15·5° C., not less than 1·4700 nor more than 1·4718; Maumené number between 42 and 52; iodine absorption number (using Hanus solution) between 77 and 94; saponification number (Koettstorfer number) between 185·0 and 195·0; free fatty acids not more than 3·5 per cent.

2. Cotton Seed Oil shall be the oil obtained from the seeds of cotton plants and subjected to refining processes. It shall be free from rancidity; the specific gravity, at 15·5° C., shall be between 0·9216 and 0·9300; refractive index at 25° C. not less than 1·4700 and not more than 1·4725; iodine number not less than 104 nor more than 116.

3. Cacao Butter, Coco Butter, shall be the edible fat obtained from sound cacao beans either before or after roasting.

4. Coconut Oil, Copra Oil, shall be the edible oil obtained from the kernels of coconuts.

5. Cochin Oil shall be coconut oil prepared in Cochin (Malabar).

6. Ceylon Oil shall be coconut oil prepared in Ceylon.

7. Corn Oil, Maize Oil, shall be the edible oil obtained from the germ of Indian corn (maize, *Zea mays* L.)

8. Palm Kernel Oil shall be the edible oil obtained from the kernels of the fruit of the palm tree (*Elaeis guineensis,* L.).

9. Peanut Oil, Arachis Oil, Earthnut Oil, shall be the edible oil obtained from the peanut (*Arachis hypogaea* L.).

10. Poppy Seed Oil shall be the edible oil obtained from the seeds of the poppy (*Papaver somniferum* L.).

11. Rape Seed Oil, Colza Oil, shall be the edible oil obtained from the seeds of the rape plant (*Brassica*).

12. Soy Bean Oil, Soja Oil, shall be the edible oil obtained from the seeds of the soy bean plant (*Dolichos soja* L., *Soja hispida* Sieb et Zucc., *Soja japonica* Savilk, *Glycine hispida* Maxim, *Glycine Soja* L.).

13. Sesame Oil, Gingili Oil, Teel Oil, Benne Oil, shall be the edible oil, obtained from the seed of the sesame plant (*Sesamum indicum,* DeC. *Sesamum orientale* L., *Sesamum radiatum* Schum and Thonn)

14. Sunflower Oil shall be the edible oil obtained from the seeds of the sunflower (*Helianthus annuus* L.).

15. Salad Oil, Table Oil. Any of the above may be sold as Salad Oil or Table Oil, but when offered for sale as Salad Oil or Table Oil, the specific name of the oil shall be declared on the label in type of the same size as the word "Salad" or the word "Table."

16. Shortening, other than butter, lard or lard compound, shall be a combination of edible animal or vegetable fats or edible oils variously processed by hydrogenation or otherwise. It shall be free from rancidity, objectionable tastes or odours, and shall contain not more than one per cent of substances other than fatty acids and their glycerides.

VI. Flavouring Extracts

1. A flavouring extract, flavouring essence, flavour, flavouring, or other preparation intended for the purpose of flavouring food, shall be a solution of correct strength, as hereinafter defined, of sapid and odorous principles derived from an aromatic plant or parts of a plant, with or without its natural colouring matters; and shall conform in name to the plant used in its manufacture.

The flavouring extracts herein described shall not be confused with similar pharmaceutical preparations described in a recognized pharmacopoeia or in a generally recognized standard work on materia medica or drugs.

2. The solvents employed in the preparation of flavouring extracts shall be ethyl alcohol, water and glycerine.

3. Solutions of natural or synthetic preparations such as vanillin, coumarin, benzaldehyde, methyl salicylate or other sapid and odorous compounds, more or less resembling substances found in plants, or identical with them, if harmless to health, may be sold for flavouring purposes, if so labelled as to make it quite clear that they are not extracts as above defined. The word "Artificial" or the word "Imitation" shall appear on the main panel of the main label in type as large and conspicuous as that used in any other word on the label.

4. Almond Extract shall be the flavouring extract prepared from oil of bitter almonds free from hydrocyanic acid, and shall contain not less than one (1) per cent by volume of oil of bitter almonds.

4a. Oil of Bitter Almonds, commercial, shall be the volatile oil obtained from the seed of the bitter almond (*Amygdalus communis* L.), the apricot (*Prunus armeniaca* L.) or the peach (*Amygdalus persica* L.).

5. Anise Extract shall be the flavouring extract prepared from oil of anise, and shall contain not less than three (3) per cent by volume of oil of anise.

5a. Oil of Anise shall be the volatile oil obtained from the anise seed.

6. Celery Seed Extract shall be the flavouring extract prepared from celery seed or the oil of celery seed, or both, and shall contain not less than three-tenths (0·3) per cent by volume of oil of celery seed.

7. Cassia Extract shall be the flavouring extract prepared from oil of cassia, and shall contain not less than two (2) per cent by volume of oil of cassia.

7a. Oil of Cassia shall be the lead-free volatile oil obtained from the leaves or bark of *Cinnamomum cassia* B. and shall contain not less than eighty (80) per cent by weight of cinnamic aldehyde.

8. Cinnamon Extract shall be the flavouring extract prepared from oil of cinnamon, and shall contain not less than two (2) per cent by volume of oil of cinnamon.

8a. Oil of Cinnamon shall be the lead-free volatile oil obtained from the bark of the Ceylon cinnamon (*Cinnamomum zeylanicum* Breyne) and shall contain not less than sixty-five (65) per cent by weight of cinnamic aldehyde and not more than ten (10) per cent by weight of eugenol.

9. Clove Extract shall be the flavouring extract prepared from oil of cloves, and shall contain not less than two (2) per cent by volume of oil of cloves.

9a. Oil of Cloves shall be the lead-free, volatile oil obtained from cloves.

10. Ginger Extract shall be the flavouring extract prepared from ginger, and shall contain in one hundred (100) cubic centimetres, the alcohol-soluble matters from not less than twenty (20) grams of ginger.

11. Lemon Extract shall be the flavouring extract prepared from lemon peel, or from oil of lemon, and shall contain along with more or less of the terpenes of lemon oil, not less than two-tenths (0·2) per cent of citral derived from oil of lemon.

12. Nutmeg Extract shall be the flavouring extract prepared from oil of nutmeg, and shall contain not less than two (2) per cent by volume of oil of nutmeg.

12a. Oil of Nutmeg shall be the volatile oil obtained from nutmegs.

13. Orange Extract shall be the flavouring extract prepared from orange peel, oil of orange, or terpeneless oil of orange, and shall correspond in flavouring strength to an alcoholic solution containing five (5) per cent by volume of oil of orange.

13a. Oil of Orange shall be the volatile oil obtained by expression or alcoholic solution, from the fresh peel of the orange (*Citrus aurantium* L.) and shall have an optical rotation (25° C.) of not less than 95° in a 100 millimeter tube.

13b. Terpeneless Oil of Orange shall be oil of orange from which all or nearly all of the terpenes shall have been removed.

14. Peppermint Extract shall be the flavouring extract prepared from oil of peppermint, or from

peppermint or both, and shall contain not less than three (3) per cent by volume of oil of peppermint.

14a. Peppermint shall be the leaves and flowering tops of *Mentha piperita* L. or of *Mentha arvensis* DeC., var *piperascens,* Holmes.

14b. Oil of Peppermint shall be the volatile oil obtained from peppermint, and shall contain not less than fifty (50) per cent by weight of menthol.

15. Rose Extract shall be the flavouring extract prepared from otto of roses, with or without red rose petals, and shall contain not less than four-tenths (0·4) per cent by volume of otto of roses.

15a. Otto of Roses shall be the volatile oil obtained from the petals of *Rosa damascena* Mill., *R. centifolia* L. or *R. moschata* (Herrm.)

16. Savory Extract shall be the flavouring extract prepared from oil of savory, or from savory, or both, and shall contain not less than thirty-five hundredths (0·35) per cent by volume of oil of savory.

16a. Oil of Savory shall be the volatile oil obtained from savory.

17. Spearmint Extract shall be the flavouring extract prepared from oil of spearmint, or from spearmint, or both, and shall contain not less than three (3) per cent by volume of oil of spearmint.

17a. Spearmint shall be the leaves and flowering tops of *Mentha spicata* L.

17b. Oil of Spearmint shall be the volatile oil obtained from spearmint.

18. Star Anise Extract shall be the flavouring extract prepared from oil of star anise, and shall contain not less than three (3) per cent by volume of oil of star anise.

18a. Oil of Star Anise shall be the volatile oil distilled from the fruit of the star anise (*Illicium verum,* Hook).

19. Sweet Basil Extract shall be the flavouring extract prepared from oil of sweet basil, or from sweet basil, or both, and shall contain not less than one-tenth (0·1) per cent by volume of oil of sweet basil,

19a. Sweet Basil, Basil, shall be the leaves and tops of *Ocymum basilicum* L.

19b. Oil of Sweet Basil shall be the volatile oil obtained from basil.

20 Sweet Marjoram Extract, Marjoram Extract, shall be the flavouring extract prepared from oil of marjoram, or from marjoram, or both, and shall contain not less than one (1) per cent by volume of oil of marjoram.

20a. Oil of Marjoram shall be the volatile oil obtained from marjoram.

21. Thyme Extract shall be the flavouring extract prepared from oil of thyme, or from thyme, or both, and shall contain not less than two-tenths (0·2) per cent by volume of oil of thyme.

21a. Oil of Thyme shall be the volatile oil obtained from thyme.

22. Tonka Extract shall be the flavouring extract prepared from the tonka bean, with or without sugar or glycerine, and shall contain not less than one-tenth (0·1) per cent by weight of coumarin extracted from the tonka bean, together with a corresponding proportion of the other soluble matters thereof.

22a. Tonka Bean shall be the seed of *Coumarouna odorata* Aublet, *Dipteryx odorata* (Aubl.) (Willd.).

23. Vanilla Extract shall be the flavouring extract prepared from the vanilla bean with or without sugar or glycerine, and shall contain in one hundred (100) cubic centimetres the soluble matters from not less than ten (10) grams of the vanilla bean (the dried, cured fruit of *Vanilla planifolia* Andrews).

24. Vanilla Extract shall contain no colouring matter other than that supplied by the vanilla bean itself.

25. Artificial and Compound Extracts of Vanilla may contain added colour, provided that declaration of such colour be made by the use of the word "Coloured" on the main panel of the main label in easily legible type.

26. Wintergreen Extract shall be the flavouring extract prepared from oil of wintergreen, and shall contain not less than three (3) per cent by volume of oil of wintergreen.

26a. Oil of Wintergreen shall be the volatile oil distilled from the leaves of *Gaultheria procumbens* L., or from *Betula lenta* L.

VII. Fruit and Fruit Products

1. Fruit shall be the clean, sound, edible, fleshy fructification of a plant, distinguished by its sweet, acid and ethereal flavour.

2. Dried Fruit shall be the clean, sound product made by drying matured, properly prepared fresh fruit in such a way as to take up no harmful substances, and shall conform in name to the fruit used in its preparation.

3. Evaporated Fruit shall be dried fruit in preparation of which artificial heat has been employed.

4. Evaporated Apples shall contain not more than twenty-five (25) per cent of moisture. (For method see Section XVIII).

5. Canned Fruit shall be the sound product made by sterilizing clean, sound, properly matured and prepared fresh fruit, by heating with or without sugar, and keeping in suitable clean containers, closed hermetically or otherwise, and shall conform in name to the fruit used in its preparation.

6. Any descriptive terms applied to dried, evaporated or canned fruit, upon the label or otherwise, shall be consistent with the definition of such terms as established by Order in Council under the Meat and Canned Foods Act.

7. Jam, Marmalade, (other than Citrus Fruit Marmalade), shall be the sound product made by processing properly prepared fresh fruit, fruit pulp or canned fruit, with water and sugar or invert sugar syrup, by boiling to a suitable consistency, with or without the addition of other ingredients such as fruit acid, preservative, colouring matter or pectin in the form of fruit juice or pectin preparations. Jam, Marmalade, shall conform in name to the fruit used in its preparation and shall contain not less than sixty-six per cent (66%) of water-soluble solids, as estimated by the refractometer.

8. Jam, Marmalade, described as "pure", "genuine", or by other terms implying a product of best quality or highest grade shall contain no ingredient other than fruit and sugar or invert sugar syrup.

9. Strawberry Jam designated as "pure", "genuine", or described by terms indicating a product of best quality or highest grade shall contain not less than fifty-five per cent (55%) of strawberries.

10. Any jam other than strawberry jam, or any marmalade other than citrus fruit marmalade, made with a single fruit and designated as "pure", "genuine", or described by terms indicating a product of best quality or highest grade shall contain not less than fifty per cent (50%) of fruit.

11. Any jam or marmalade made by incorporating with a fruit and sugar (crystallized or invert) any other ingredient or ingredients such as other fruit juice, pectin preparation, fruit acid, colouring matter or preservative, shall be labelled to indicate its true character by specifying on the label, plainly and correctly, the nature of such addition. The words "pure", "genuine", or their equivalent, shall not be used to describe it.

12. Strawberry jam of any grade other than pure or genuine shall contain not less than thirty-two per cent (32%) of strawberries. Jam or marmalade other than citrus fruit marmalade, of any grade or quality other than pure or genuine, made with a single fruit other than strawberry, shall contain not less than twenty-seven per cent (27%) of fruit.

13. Jam or marmalade other than citrus fruit marmalade, made from two or more kinds of fruit, one of which is strawberry, shall contain not less than fifteen per cent (15%) of strawberries. Any other jam or marmalade made with two or more kinds of fruit shall contain not less than twelve and one-half per cent (12½%) of the most expensive fruit named on the label. In naming any such jam or marmalade the fruit present in greatest proportion shall be mentioned first.

14. Preserve shall be the sound product made by processing fruit with sugar or with invert sugar syrup and shall contain no other ingredients. In its preparation not less than forty-five (45) pounds of fruit shall be used with each fifty-five (55) pounds of sugar, or its equivalent in invert sugar syrup.

15. Citrus Fruit Marmalade shall be the sound product of jelly-like consistency made from citrus fruits, containing any combination of peel, pulp and juice, by boiling with water and sugar or invert sugar syrup, and shall contain no other ingredient.

16. Jelly shall be the sound semi-solid, gelatinous product made by boiling a clean, sound, properly

prepared fruit and water, concentrating the expressed and strained juice to which sugar shall be added, with or without other ingredients such as fruit acid, the juice of another fruit, pectin preparation, colour-matter, agar, gelatin, or preservative.

17. Jelly shall contain not less than sixty-two per cent (62%) water-soluble solids, as estimated by the refractometer.

18. Jelly, Fruit Jelly, described as "pure", "genuine", or by other term implying a product of best quality or highest grade, shall contain no ingredient other than a fruit juice and sugar or invert sugar syrup.

19. Any jelly made by incorporating with a fruit juice and sugar, any other ingredient, or ingredients, shall be labelled to indicate its true character by specifying on the label, plainly and correctly, the nature of such addition. The words "pure" or "genuine", or their equivalent, shall not be used to describe it.

20. Mince, Mince Meat shall be a mixture of chopped suet, apple and other fruit, salt and spices, with sugar, syrup or molasses, and with or without vinegar, fresh, concentrated or fermented fruit juices, or spirituous liquors, or cooked, comminuted meat.

VIII.—Grain Products

1. Grain shall be the fully matured, clean, sound air-dry seed of wheat, maize, rice, oats, rye, buck-wheat, barley, sorghum, millet or spelt.

2. Meal shall be the clean, sound product made by grinding grain.

3. Flour shall be the fine, clean, sound product made by bolting wheat meal, and shall contain not more than thirteen and five-tenths (13·5) per cent of moisture, not less than one and twenty-five hundredths (1·25) per cent of organic nitrogen, nor more than two (2) parts per million of nitrite reacting nitrogen, not more than one (1) per cent of ash, and not more than fifty hundredths (0·50) per cent of fibre.

4. Bleached Flour shall be flour which has under-gone processing for the purposes of making it lighter in colour. The residual nitrite reacting nitrogen shall not exceed five (5) parts per million. The

presence of more than two (2) parts per million of nitrite reacting nitrogen in flour shall be held to be proof of its having been bleached by oxides of nitrogen.

Note.—Nitrite reacting nitrogen shall be calculated as Sodium Nitrite ($NaNO_2$) which for the purposes of this definition shall be identical with nitrogen.

5. Ground Gluten shall be the clean, sound product made from wheat flour, by removal of starch, and shall contain not more than ten (10) per cent of moisture, and calculated on the water-free basis, not less than fourteen and two-tenths (14·2) per cent of nitrogen, not more than fifteen (15) per cent of nitrogen-free extracts (using protein factor 5·7) and not more than five and five-tenths (5·5) per cent of starch, as determined by the diastase method.

6. Gluten Flour shall be the clean, sound product made from wheat flour by the removal of a large part of the starch, and shall contain not more than ten (10) per cent of moisture, and, calculated on the water-free basis, not less than seven and one-tenth (7·1) per cent of nitrogen, not more than fifty-six (56) per cent of nitrogen-free extract (using protein factor 5·7) and not more than forty-four (44) per cent of starch, as determined by the diastase method.

7. Diabetic Foods offered for sale as breads, biscuits, cakes or otherwise, shall contain not more than half as much glycogenic carbohydrates as the normal food of the same class. Any statement on the label or in advertisement which gives the impression that any single food in unlimited quantity is suitable for the diabetic patient, shall be held to be false and misleading.

8. Maize Meal, Corn Meal, Indian Meal shall be meal made from sound maize grain, and shall contain not more than fourteen (14) per cent of moisture, not less than one and twelve-hundredths (1·12) per cent of organic nitrogen, and not more than one and six-tenths (1·6) per cent of ash.

9. Rice shall be the hulled, or hulled and polished grain of *Oryza sativa*.

10. Rice Flour shall be the clean, sound product made by bolting rice meal, and shall contain not

more than fifteen (15) per cent of moisture, not less than one (1) per cent of organic nitrogen, and not more than one (1) per cent of ash.

11. Oatmeal shall be meal made from hulled oats, and shall contain not more than twelve (12) per cent of moisture, not more than one and eight-tenths (1·8) per cent of crude fibre, not less than two (2) per cent of organic nitrogen, and not more than two and two-tenths (2·2) per cent of ash.

12. Rye Flour shall be the fine, clean, sound product made by bolting rye meal, and shall contain not more than thirteen and five-tenths (13·5) per cent of moisture, not less than one and thirty-six hundredths (1·36) per cent of organic nitrogen, and not more than one and twenty-five hundredths (1·25) per cent of ash.

13. Buckwheat Flour shall be bolted buckwheat meal, and shall contain not more than twelve (12) per cent of moisture, not less than one and twenty-eight hundredths (1·28) per cent of organic nitrogen, and not more than one and seventy-five hundredths (1·75) per cent of ash.

14. Corn starch shall be the starch obtained from maize or Indian corn (*Zea mays*) and shall contain not less than eighty-four (84) per cent of actual starch, and not more than thirteen (13) per cent of moisture, and not more than one (1) per cent of ash, and not more than two (2) per cent of substances other than starch and moisture.

15. Noodles, or any other alimentary paste such as macaroni, etc. if offered for sale or sold as a product containing egg, shall contain on the moisture-free basis, not less than five and five-tenths (5·5) per cent of the solids of egg or of egg yolk.

IX.—Meat, Meat Products and Meat By-Products

1. Any descriptive terms applied to any meat, meat by-product or to any preparation of either of them upon the label or otherwise, shall be consistent with the definition of such terms as established under the Meat and Canned Foods Act.

2. Preservatives other than those mentioned in Class 1, Section XII, or colouring matter, shall not be used in or upon meat, meat by-products or any preparation of either of them.

A. Meats

1. Meat shall be the clean, sound, properly dressed flesh of one or more animals healthy at the time of slaughter and shall include the heart, tongue, diaphragm and oesophagus in addition to the skeletal musculature with attendant tissues. The term "Animals,' as herein used, shall include not only mammals, but fish, fowls, crustaceans, mollusks and other animals used as food.

2. Fresh meat shall be meat from animals recently slaughtered and properly cooled until delivered to the consumer.

3. Cold Storage Meat shall be meat from animals recently slaughtered and preserved by refrigeration until delivered to the consumer.

4. Salted, Pickled and Smoked Meats shall be unmixed meats preserved by salt, sugar, vinegar, spices and other harmless substances, or smoke, singly or in combination, whether in bulk or in suitable containers.

4*a*. Suitable containers for keeping moist food products such as syrups, honey, condensed milk, soups, meat extracts, meat, manufactured meats and undried fruits and vegetables, and wrappers in contact with food products, shall contain on their surfaces in contact with food products, no lead, antimony, arsenic, zinc, or copper, or any compounds thereof or any other poisonous or injurious substances. If the containers are made of tin plate, they shall be outside soldered, or if soldered inside, the solder used shall consist of pure tin only; and the plate in no place shall contain less than one hundred and thirteen (113) milligrams of tin on a piece five (5) centimetres square or one and eight-tenths (1·8) grains on a piece two (2) inches square.

This is equivalent to two (2) pounds of tin per base box; but it must be noted that the regulation requires not only a minimum weight of tin per base box, but that this tin shall be evenly distributed over the surface of the plate.

The inner coating of the containers shall be free from pin holes, blisters and cracks.

If the tin plate is lacquered, the lacquer shall completely cover the lined surface within the container and yield to the contents of the container no lead,

antimony, arsenic, zinc or copper, or any compounds thereof, or any other poisonous or injurious substances.

5. Shucked oysters shall not contain more than ten (10) per cent of fluid separable by drainage on a ten-mesh sieve.

B. Manufactured Meats

1. Manufactured Meats shall be meats not included in paragraphs 2, 3 and 4 of Subsection A, whether simple or mixed, whole or comminuted, in bulk or in suitable containers, with or without the addition of salt, vinegar, sugar, spices, or other harmless substances, smoke, oils or rendered fat. If they bear names descriptive of kind, composition, or origin, they correspond thereto, and when bearing such descriptive names, if force or flavouring meats are used the kind and quantity thereof shall be made known.

2. Sausage, Sausage Pudding, etc., shall be a comminuted meat or a mixture of such meats, either fresh, salted, pickled or smoked, with added salt and spices, and with or without the addition of edible animal fats, cereals, beef tripe, liver, blood or sugar, and with or without subsequent smoking. It shall contain no larger amount of water than the meats from which it is prepared contain when in their fresh condition, and this must not exceed sixty (60) per cent, and not more than five (5) per cent of its weight of cereals, and if it bears a name descriptive of kind, composition or origin, it shall correspond to such descriptive name. All animal tissues used as containers, such as casings, stomachs, etc., shall be clean and sound and impart to the contents no substance other than salt.

3. Blood Sausage, Blood Pudding, shall be sausage to which has been added clean fresh blood from neat cattle or swine in good health at the time of slaughter.

4. Canned Meat shall be the cooked meat of fowls, neat cattle or swine, preserved in packages closed hermetically or otherwise.

5. Corned or Cured Meat shall be meat cured or pickled with dry salt or in brine, with or without the addition of sugar or other harmless substances.

6. Potted Meat shall be comminuted and cooked meat, with or without salt and spices, and enclosed in suitable containers closed hermetically or otherwise. Cereals when present must not exceed five (5) per cent by weight.

7. Meat Loaf shall be a mixture of comminuted cooked meat, with or without spices, cereals, milk or eggs, pressed into a loaf. If it bears a descriptive name it shall correspond thereto. Meat Loaf shall not contain more than five (5) per cent of cereals.

8. Mince, Mince Meat—See Fruit Products, Section VII.

C. Meat Extracts, Meat Peptones, Gelatin, etc.

1. Meat Extract shall be the product obtained by extracting fresh meat with water and concentrating the liquid portion by evaporation after the removal of fat, and shall contain not less than seventy-five (75) per cent of total solids of which not over twenty-seven (27) per cent shall be ash, and not over twelve (12) per cent shall be sodium chloride (calculated from the total chlorine present), not over six-tenths (0·6) per cent shall be fat and not less than eight (8) per cent shall be nitrogen. The nitrogenous compounds shall contain not less than forty (40) per cent of meat bases and not less than ten (10) per cent of creatin and creatinin.

2. Fluid Meat Extract shall be identical with meat extract except that it shall be concentrated to a lower degree and contain not more than seventy-five (75) and not less than fifty (50) per cent of total solids.

3. Bone Extract or Stock shall be the product obtained by extracting clean, fresh, trimmed bones of animals in good health at the time of slaughter, with boiling water and concentrating the liquid portion by evaporation after removal of the fat, and shall contain not less than seventy-five (75) per cent of total solids.

4. Fluid Bone Extract shall be identical with bone extract except that it shall be concentrated to a lower degree and contain not more than seventy-five (75) and not less than fifty (50) per cent of total solids.

5. Meat Juices shall be the fluid portion of muscle fibre obtained by pressure or otherwise, and may be concentrated by evaporation at a temperature below the coagulating point of the soluble proteins. The solids shall contain not more than fifteen (15) per cent of ash, not more than two and five-tenths (2·5) per cent of sodium chloride (calculated from the total chlorine present), not more than four (4) and not less than two (2) per cent of phosphoric acid (P_2O_5) and not less than twelve (12) per cent of nitrogen. The nitrogenous compounds shall contain not less than thirty-five (35) per cent of coagulable proteins and not more than forty (40) per cent of meat bases.

6. Peptones shall be products prepared by the digestion of protein material by means of enzymes or otherwise, and shall contain not less than ninety (90) per cent of proteoses and peptones.

7. Gelatin (edible gelatin) shall be the purified dried inodourous product of the hydrolysis by treatment with boiling water, of certain tissues, as skin, ligaments, and bones, from sound animals, and shall contain not more than two (2) per cent of ash and not less than fifteen (15) per cent of nitrogen.

D. Lard

1. Lard shall be the rendered fat from hogs in good health at the time of slaughter, shall be clean, free from rancidity, and contain necessarily incorporated in the process of rendering not more than one (1) per cent of substance other than fatty acids and fat.

2. Leaf Lard shall be lard rendered at moderately high temperature from the internal fat of the abdomen of the hog, excluding that adherent to the intestines, and shall have an iodine number not greater than sixty-five (65) and contain not more than one (1) per cent of substances other than fatty acids and fat.

3. Compound Lard, Lard Compound, etc., shall be a mixture of animal and vegetable fats and oils. It shall be free from rancidity, be made from sound and pure materials and contain not more than one (1) per cent of substances other than fatty acids

and fat, and at least fifty-one (51) per cent of actual lard shall be present in the article.

E.—Meat By-Products

1. Meat By-Products shall be the clean, sound, edible parts other than meat, derived from one or more animals healthy at the time of slaughter and shall include the tissue residues from the processes whereby edible fats are rendered.

2. Prepared Meat By-Products shall be wholesome articles made wholly or in part from comminuted meat by-products with or without cereal, seasoning and Class I preservatives. All prepared meat by-products, other than such varieties of sausage as contain beef tripe or liver, or both, shall be clearly and distinctly labelled as such.

X.—Metallic Impurities in Food

Arsenic (arsenious oxide, As_2O_3) shall not be present in herein named articles, in excess of the following amounts:—

	Parts per million
Citric Acid	1
Tartaric Acid	1
Cream of Tartar	2
Sodium Bicarbonate	2
Phosphoric Acid	5
Calcium Phosphate	5
Sodium Phosphate	5
Boric (Boracic) Acid	4
Baking Powder	2
Coal Tar Colour used in Food	10

Zinc shall not be present in foods in excess of the following amounts:—

	Parts per million
Dried Egg Products	150

XI.—Milk Products

1. Sterilized Milk shall be milk that has been heated without concentration or appreciable loss of volume to the temperature of boiling water, or above this temperature, for a length of time sufficient to kill all organisms present, and shall be delivered to the consumer in sterile condition. Steri-

lized milk shall contain not less than three and twenty-five hundredths (3·25) per cent of milk fat, and not less than eleven and seventy-five hundredths (11·75) per cent of total milk solids and the label shall bear the words "this milk is not a concentrated product, but has only the food value of normal milk." Sterilized milk shall not be sold or offered for sale except in hermetically sealed containers, bearing the words "this milk should be used within twelve hours after opening the container."

2. Condensed Milk (sweetened condensed milk) shall be milk from which a considerable portion of water shall have been evaporated, and to which sugar shall have been added. It shall contain, all tolerances being allowed for, not less than twenty-eight (28) per cent of milk solids and not less than eight (8) per ment of milk fat.

3. Evaporated Milk (unsweetened condensed milk) shall be milk from which a considerable portion of water shall have been evaporated, and shall contain, all tolerances being allowed for, not less than twenty-five and five-tenths (25·5) per cent of milk solids, and not less than seven and eight-tenths (7·8) per cent of milk fat.

4. Sub-standard Concentrated Milk. It shall not be forbidden to sell milk which shall have been concentrated either with or without sugar, to a less degree than Condensed Milk or Evaporated Milk, but such milk shall be labelled Sub-standard Concentrated Milk, and neither upon the label, nor upon any descriptive matter, shall it be described as Condensed Milk, Evaporated Milk or Sterilized Milk, because these terms are legally defined.

Sub-standard Concentrated Milk shall be labelled in such a way as correctly to inform the purchaser regarding its content in milk fat, and in total milk solids.

5. Skimmed Milk, Separated Milk (machine skimmed milk), etc., may be sold in condensed form, essentially resembling the articles made from whole milk, and described in paragraphs 2 and 3 above, with the difference that they do not contain milk fat.

In all these products the word "Skimmed" shall appear on the label in letters the same size as used in the word "Milk".

6. Condensed Skimmed Milk, Condensed Separated Milk (machine skimmed milk) shall be skimmed milk or separated (machine skimmed) milk from which a considerable portion of water shall have been evaporated, and to which sugar shall have been added. It shall contain, all tolerances being allowed for, not less than twenty-eight (28) per cent of milk solids.

7. Milk Fat, Butter Fat, shall be the fat of milk and if that of cow's milk shall have a Reichert-Meissl number not less than twenty-four (24), a specific gravity not less than 0·905 at 40°C. If the Polenske number exceeds ten (10) per cent of the Reichert-Meissl number such shall be taken as evidence of the addition of fat other than that of cow's milk.

8. Butter shall be the clean product made by gathering in any manner the fat of fresh or ripened milk or cream, preferably pasteurized, into a mass which also shall contain a small portion of the other milk constituents, with or without salt, and shall contain not less than eighty (80) per cent of milk fat, and not more than sixteen (16) per cent of water. Butter may also contain added colouring matter.

9. Whey Butter shall be butter which shall have been recovered from whey, a by-product of the manufacture of cheese. Whey Butter must possess the same fat content, and the same limit for water as butter above defined, and must be labelled "Whey Butter."

10. Cheese shall be the sound product made from curd obtained from milk, skim-milk, cream or any mixture of these by coagulating the casein thereof with rennet, lactic acid or other suitable enzyme or acid, and with or without further treatment by suitable processes and with or without the addition of proportionately small amounts of other wholesome ingredients such as other milk solids, ripening ferments, special moulds, emulsifying agents, seasoning or colouring matter.

10*a*. Cheese which has been processed with the use of emulsifying agents shall contain not more than forty-three (43) per cent moisture.

11. Cheese made from or by the use of skim-milk or milk from which any cream has been removed or milk to which skim-milk has been added, or any cheese containing in the water-free substance less than forty-five (45) per cent of milk fat, shall be labelled as skim-milk cheese.

12. Ice Cream shall be the iced product, free from taints and objectionable flavours, prepared with cream and sugar (sucrose) with or without milk or other milk products.

Ice Cream may contain fruit, fruit juice, nuts, colourings, flavourings, thickeners, stabilizers.

Thickeners and stabilizers, such as starch, gelatin and gum tragacanth, shall not be employed in a proportion higher than two (2) per cent.

Ice Cream shall contain not less than ten (10) per cent of milk fat. Fat other than milk fat shall not be employed in its manufacture.

All milk and cream used in the manufacture of ice cream should, if possible, be previously pasteurized and emulsified.

When sold in a package prepared by the manufacturer, the outer container shall be labelled to indicate the name and the address of the manufacturer and shall bear a statement as to whether or not the contents have been pasteurized.

When sold or dispensed from tanks, cans or other containers such receptacles shall be labelled to indicate the name and the address of the manufacturers and shall bear a statement as to whether or not the contents have been pasteurized.

Ice Cream which has melted and been refrozen may be injurious to the health of the consumer and, therefore, shall not be offered for sale nor sold. (See Section 4 (*f*) of the Food and Drugs Act.)

13. Whey shall be the product remaining after the removal of fat and casein from milk in the process of cheese-making.

14. Kumiss shall be the product made by the alcoholic fermentation of mare's milk or cow's milk.

15. Milk Powder shall be the soluble powder product made from milk and shall contain not less than ninety-five (95) per cent of milk solids, and not less than twenty-six (26) per cent of milk fat.

16. Skimmed Milk Powder, Separated (machine skimmed) Milk Powder, shall be the soluble powder product made from skimmed milk, separated (machine skimmed) milk and shall contain not less than ninety-five (95) per cent of milk solids. The word "Skimmed" shall appear on the label in letters the same size as those used in the word "Milk".

17. Malted Milk shall be the product made by combining whole milk with the liquid separated from a mash of ground barley malt and meal, with or without the addition of sodium chloride, sodium bicarbonate or potassium bicarbonate, in such a manner as to secure the full enzyme action of the malt extract and by removing water. The resulting product shall contain not less than seven and five-tenths (7·5) per cent of milk fat, and not more than three and five-tenths (3·5) per cent of moisture.

18. Canned Homogenized Milk shall be milk which shall have been treated by a homogenizer before canning, and shall contain not less than three and twenty-five hundredths (3·25) per cent of milk fat, and not less than eleven and seventy-five hundredths (11·75) per cent of total milk solids.

Canned Homogenized Milk shall be plainly labelled as such.

XII. Preservatives

Foods intended for export may contain preservatives provided that both in specific character and in amount, such preservatives do not conflict with regulations in force in the country to which export shall be made.

No preservatives whatever may be used in milk.

Class I

No preservatives other than those in this class may be used in or upon meat or meat products, or foods intended for infants or invalids.

1. Common Salt.
2. Sugar.
3. Saltpetre.
4. Wood Smoke.
5. Vinegar.
6. Spices.
7. Alcohol.
8. Refined Sodium Nitrate.
9. Refined Sodium Nitrite in cured meats, not to exceed 200 parts per millon in the finished product.

Class II

Until further notice the preservatives of this class may be used in certain foods but not in those in which such preservatives are prohibited elsewhere in these Regulations, provided that not more than one kind of preservative substance named in this list shall be added to any one kind of food or to any mixture of two or more kinds of food; provided also that the amount of preservative shall not exceed the limit herein specified, and the presence of the preservative shall be declared by name, on the main panel of the main label, in easily legible type.

Regarding this class of preservatives it is to be noted that toleration of their use is dependent upon the fact that available evidence concerning their physiological action is not considered sufficient to prove that, under the prescribed regulations, they are harmful to health in such degree as to bring them under Section 4 (*f*) of the Food and Drugs Act, which reads as follows:—

"Food shall be deemed to be adulterated within the meaning of this Act, if it contains any added poisonous ingredient, or any ingredient which may render it injurious to the health of the person consuming it, whether added with intent or otherwise."

Should satisfactory evidence of the harmfulness to health of any of the preservatives named in Class II be forthcoming, such preservatives would immediately fall under the condemnation of the Food and Drugs Act, and foods containing such preservatives would be declared to be adulterated.

1. Benzoic Acid or its salts.
   Limit: 1 part (calculated as benzoic acid) in 1,000 parts.
2. Sulphurous Acid or its salts.
   Limit: 1 part (SO_2) in 10,000 parts in beverages.
   Limit: 1 part (SO_2) in 2,000 parts in solid foods.
   Limit: 1 part (SO_2) in 2,000 parts in lime juice.
   Limit: 4 parts (SO_2) in 2,000 parts in dried fruits.

Class III

Foods shall not contain preservatives of this class:

1. Formaldehyde (Formalin).
2. Beta-Naphthol.
3. Abrastol (Asaprol).
4. Fluorine Compounds.

5. Saccharin and similar synthetic compounds (except in such foods as may be prepared for the exclusive use of persons suffering from disease, such preparation being preferably under skilled direction).

XIII.—Spices, Etc.

A. Cloves

Cloves shall be the dried flower buds of *Caryophyllus aromaticus* L., which shall contain not more than five (5) per cent of clove stems, not less than fifteen (15) per cent of volatile ether extract, not more than eight (8) per cent of total ash, not more than five-tenths (0·5) per cent of ash insoluble in hydrochloric acid, and not more than ten (10) per cent of crude fibre.

B. Ginger

1. Ginger shall be the washed and dried or decorticated and dried rhizome of *Zingiber officinale* Roscoe. It shall contain not more than ten (10) per cent of moisture, and in the water-free substance not less than forty-five (45) per cent of starch, not more than nine (9) per cent of fibre, not more than one (1) per cent of lime (CaO), not more than seven and five-tenths (7·5) per cent of total ash, not more than two (2) per cent of ash insoluble in hydrochloric acid, not less than two (2) per cent of ash soluble in water, and not less than thirteen and three-tenths (13·3) per cent of cold water extractive as determined by the method defined in Section XVIII.

2. Jamaica Ginger shall be ginger grown in Jamaica. It shall conform to all the mineral standards for ginger, and shall yield at least sixteen and six-tenths (16·6) per cent of cold water extractive.

3. Limed Ginger or Bleached Ginger shall be ginger coated with calcium carbonate. It shall conform to the standards for ginger, as above, but may contain not more than eleven (11) per cent of total ash, and not more than two (2) per cent of lime (CaO).

C. Mustard

Mustard, Mustard Flour, Ground Mustard, shall be the powder made from mustard seed with the hulls largely removed and with or without the re-

moval of a portion of the fixed oil. It shall contain not more than one and five-tenths (1·5) per cent of starch and not more than six (6) per cent of total ash.

D. Pepper

1. Black Pepper shall be the dried immature berry of *Piper nigrum* L. and shall contain not less than six and seventy-five hundredths (6·75) per cent of non-volatile ether extract, not less than thirty (30) per cent of pepper starch, not more than seven (7) per cent of total ash, and not more than one and five-tenths (1·5) per cent of ash insoluble in hydrochloric acid.

2. Ground Black Pepper shall be the product made by grinding the entire berry, as above defined. It shall contain the several parts of the berry in their normal proportions and shall conform in its composition to the standards as above for black pepper.

3. White Pepper shall be the dried mature berry of *Piper nigrum* L. from which the outer coating, or the outer and inner coatings shall have been removed. It shall contain not less than seven (7) per cent of non-volatile ether extract, not less than fifty-two (52) per cent of pepper starch, not more than five (5) per cent of crude fibre, not more than three and five-tenths (3·5) per cent of total ash, and not more than three-tenths (0·3) per cent of ash insoluble in hydrochloric acid.

4. Ground White Pepper shall be the product made by grinding the berry as above defined, and shall conform in its composition to the standards as above for white pepper.

5. Cayenne Pepper, Cayenne, shall be the dried ripe fruit of *Capsicum frutescens* L., *Capsicum baccatum* L., or some other small-fruited species of *Capsicum*. It shall contain not less than fifteen (15) per cent of non-volatile ether extract, not more than one and five-tenths (1·5) per cent of starch, not more than twenty-eight (28) per cent of crude fibre, not more than eight (8) per cent of total ash, and not more than one and twenty-five hundredths (1·25) per cent of ash insoluble in hydrochloric acid.

XIV.—Sugar and Related Substances

A. Sucrose Products

1. Sugar shall be the product chemically known as sucrose (saccharose) and is at the present time found in commerce as obtained from sugar cane, sugar beet, sorghum, maple and palm.

2. Sugar, if sold as granulated, loaf cut, milled or powdered sugar, shall contain at least ninety-nine and five-tenths (99·5) per cent of sucrose and shall be free from any artificial neutralizing colouring matter, unless declaration of the fact is made upon the package.

3. Icing sugar shall be a powdered sugar specially prepared for use in baking and may contain starch not exceeding five (5) per cent by weight.

4. Massecuite, Melada, Raw Sugar, Concrete, etc., shall be a product made by evaporating the partially purified juice of a sugar-producing plant or a solution of sugar, to a solid or semi-solid consistency in which the sugar exists chiefly in a crystalline state.

5. Molasses shall be the product left after separating a part of the sugar from massecuite, melada, raw sugar, or concrete, and shall contain not more than twenty-five (25) per cent of water and not more than five (5) per cent of ash.

6. Refiner's Syrup, Treacle, shall be the residual liquid product obtained in the process of refining raw sugar, and shall contain not more than twenty-five (25) per cent of water and not more than eight (8) per cent of ash.

7. Sugar-cane Syrup shall be syrup made by evaporation of the juice of the sugar-cane or by the solution of sugar-cane concrete, and shall contain not more than thirty (30) per cent water and not more than two and five-tenths (2·5) per cent of ash.

8. Sorghum Syrup shall be syrup made by the evaporation of sorghum juice or by the solution of sorghum concrete, and shall contain not more than thirty (30) per cent of water, and not more than two and five-tenths (2·5) per cent of ash.

9. Sugar Syrup shall be the product made by dissolving sugar to the consistency of a syrup and shall contain not more than thirty-five (35) per cent of water.

B. Glucose Products

1. Starch Sugar, Corn Sugar, Grape Sugar, shall be the solid product made by hydrolyzing starch, or a starch containing substance, until the greater part of the starch has been converted into dextrose.

2. Anhydrous Starch Sugar shall contain not less than ninety-five (95) per cent of dextrose and not more than eight-tenths (0·8) per cent of ash.

3. Hydrous Starch Sugar, Brewers' Sugar shall contain from seventy to eighty (70 to 80) per cent of dextrose and not more than two (2) per cent of ash. When sold under any name which implies a definite percentage of dextrose it must contain at least the stated percentage of that component.

4. Glucose, Mixing Glucose, Confectioners' Glucose, shall be a thick syrupy, nearly colourless product made by incompletely hydrolyzing starch, or a starch-containing substance. It shall contain not more than (2) per cent of ash.

5. Corn Syrup shall be a mixture of glucose with sugar syrup, sugar cane syrup, sorghum syrup, molasses, refiners' syrup, treacle etc., with or without the addition of harmless flavouring substances, provided that such mixture or addition does not contravene the requirements of the Maple Sugar Industry Act, 1930. It shall contain not more than thirty-five (35) per cent of water and not more than three (3) per cent of ash.

C. Honey

Honey shall be entirely the product of the work of bees operating upon the nectar of flowers and other sweet exudations of plants. It shall contain not more than twenty (20) per cent of water, not more than five (5) per cent of sucrose, not more than twenty-five hundredths (0·25) per cent of ash and not less than sixty (60) per cent of invert sugar.

XV.—Tea

Tea shall be the leaves and buds of various species of the genus *Thea* L., varieties of *Camellia Thea* Link, prepared by the usual trade processes, and shall conform in variety and place of production to the name it bears. On the moisture-free basis it

shall contain not less than four (4) per cent and not more than seven (7) per cent of total ash and not less than three (3) per cent of water-soluble ash. On the moisture-free basis, green tea shall contain not less than thirty-three (33) per cent, and black tea shall contain not less than thirty (30) per cent of water-soluble extractive as determined by the method prescribed in Section XVIII of these regulations.

XVI.—Vinegar

1. Vinegar shall be a more or less coloured liquid, consisting essentially of dilute acetic acid, obtained by the acetous fermentation of wine, beer, cider, or other alcoholic liquid. It shall contain not less than three and five-tenths (3·5) per cent and not more than ten and five-tenths (10·5) per cent of acetic acid calculated as acetic anhydride (excise practice).

2. Wine Vinegar shall be vinegar made by the alcoholic and subsequent acetous fermentation of the juice of grapes.

3. Spirit Vinegar, Alcohol Vinegar, Grain Vinegar, shall be vinegar made by the acetous fermentation of diluted distilled alcohol.

4. Malt Vinegar shall be vinegar made by the alcoholic and subsequent acetous fermentation without distillation, of an infusion of malt with or without the addition of other cereals. It shall be dextrorotatory and shall contain in one hundred (100) cubic centimetres (20° C) not less than one and eight-tenths (1·8) grams of solids and not less than two-tenths (0·2) gram of ash.

5. Cider Vinegar, Apple Vinegar, shall be vinegar made by the alcoholic and subsequent acetous fermentation of the juice of apples.

6. Vinegar may be made by the acetous fermentation of dilute alcoholic liquids, the alcohol of which may have had its origin in the fermentation of fruit sugars of various kinds or of ordinary sugar. Such vinegars should bear distinctive names indicating the sources of the materials used for the alcoholic fermentation.

7. If any vinegar is subjected to distillation after completion of the acetous fermentation, this fact must be clearly and distinctly stated on the label.

8. Blended Vinegar shall be made by mixing two or more of the above varieties of vinegar. Spirit vinegar shall not constitute more than fifty-five (55) per cent of any blended vinegar.

9. In labelling blended vinegars, if any one of the varieties of vinegar forming the blend is named, all the varieties shall be named; the names shall be printed in the same sized type and the variety first mentioned must be present in largest amount.

10. The addition of caramel or other brown or amber colouring matter to spirit vinegar or to any blended vinegar containing spirit vinegar, shall be deemed to contravene Section 7 (*d*) of the Food and Drugs Act and shall be prohibited. (See Section IV, par. 5, of these Regulations.)

XVII.—Waters (Bottled Waters)

1. Bottled Water shall be water distinguished from that of ordinary domestic supplies by being offered for sale in special containers, such as bottles, kegs, barrels, siphons, etc., and by being proprietary.

2. Mineral Water shall be bottled water characterized by having in solution notable amounts of mineral matter or other ingredients on account of which it shall be claimed to possess hygienic or therapeutic properties.

Note.—Mineral Waters are classified in various ways and very commonly as Alkaline, Chalybeate, Saline, Sulphuretted, Carbonated, Purgative, Aperient etc.

In some cases a well-known source has come to give its name to a type of mineral water, just as in the case of wines, where the terms Port, Sherry etc., imply types of wine, rather than wines of definite geographical origin.

Thus, the names Vichy, Carlsbad, Harrogate etc., may be used as types of mineral water. When so employed the label shall show the word "type" after the descriptive name; thus "Vichy type," "Harrogate type" etc.; and shall be so written as to make perfectly clear that the water does not actually come from Vichy or from Harrogate.

When the water is described as a certain type, e.g.. Vichy type, etc., it shall be required that the

composition of such water as determined by analysis, shall approximate within reasonable limits the known character of the water quoted as its type.

3. Table Water shall be bottled water characterized by exceptional purity or by containing material which shall be claimed to render it peculiarly suitable for table use. Certain mineral water, not especially active physiologically, may be offered as table water. Hence the distinctions between mineral water and table water shall not be mutually exclusive.

4. Natural bottled water offered for sale in Canada shall be labelled to indicate clearly whether the water is of Domestic (Canadian) or of Foreign origin; and the name of the actual place of production shall be clearly printed on the label.

5. Natural Bottled Water shall be a water which is bottled at its source without addition or removal of any constituent. If a natural water has been subjected to treatment such as carbonation, filtration, sterilization or dilution, a statement of the nature of the treatment shall appear on the label, or the term "Artificial" used to describe it. If such natural water has been diluted with soft water, the degree of dilution (volume of soft water added to 100 volumes of spring water or well water) shall be specified. Any natural water fortified by the addition of saline material shall be distinctly labelled as "Artificial."

6. Mineral water made by dissolving the salts supposed to be characteristic of a specific source, e.g., Vichy, Carlsbad, etc., shall be designated as Artificial, even though the salts so dissolved may themselves be obtained by actual evaporation of the water from the named source.

XVIII.—Methods for the Analysis of Certain Foods

A. *Determination of Moisture in Evaporated Apples*

A representative sample, at least 25 grams, is comminuted by cutting with a sharp knife, on a hardwood board, until the fragments are not larger than cubes of one-fourth of an inch. Machines such as

are used to cut sausage meat are objectionable, as they squeeze out more or less of the water, thus causing loss. Weigh out duplicate portions of from 10 to 15 grams, of the finely cut material, on tared watch glasses, and dry for two hours at 90° C., in a well-ventilated, water-jacketed oven. Weigh the samples and replace them in the oven for one hour. Weigh again.

If the loss of weight between the two weighings amounts to less than one-half of one per cent of the weight of the sample the last weighing is to be accepted as final, and the weight lost in three hours is to be calculated as a percentage loss on the original weight of the sample, and stated as moisture.

If in the last hour the sample has lost more than one-half of one per cent of its original weight replace it in the oven and leave for one hour, under same conditions of temperature, etc. The loss of weight in the four hours is to be taken as representing the moisture present in the original sample.

NOTE.—It is desirable to employ an oven with forced ventilation. See description of the McGill oven in Leach's "Food Inspection and Analysis."

B. *Determination of the Cold Water Extractive in Ground Ginger*

Place 10 grams of the sample in a half litre flask, and make up to 500 cc. with water at 20° C. Shake the flask at half-hour intervals for eight hours, allow to stand for sixteen hours, filter and evaporate 50 cc. of the filtrate to dryness in a flat bottomed metal dish on the water bath, then to constant weight at 100° C.

A mechanical shaker may be used instead of the hand, but if this is done, the time limits must be adjusted by experimental standardization of the machine, so that results obtained on actual samples of ginger may be identical with those obtained by the method as prescribed.

C. *Determination of Carbon Dioxide Yielded by Baking Powder*

From 1 to 2 grams of the sample is used; this is boiled with about 100 cc. water for 10 minutes from the time when boiling begins with aspiration

of a slow current of air which carries the liberated gas through a series of U-tubes, etc., arranged as follows:—

1. A short Liebig condenser, arranged so as to return the condensed steam to the boiling flask.

2. A U-tube (or tower) containing pumice saturated with concentrated sulphuric acid.

3. A smaller U-tube containing fragments of pumice saturated with concentrated sulphuric acid; or lumps of fused calcium chloride, which must be neutral.

4. A U-tube containing soda-lime; or Liebig bulbs containing 50 per cent solution of potassium hydroxide.

5. Duplicate of (4).

6. A U-tube like (3).

7. Same as (6) and connected at exit end to an aspirator or suction pump.

A-T-tube should be interposed between the exit end of number 7 and the suction. The third leg of the T-tube carries a piece of rubber tubing and a pinch cock. The suction may then be turned on full, and the rate of the air current regulated by the pinch cock.

U-tubes 3, 4, 5 and 6 are weighed. Number 3 should not materially gain weight, and serves to protect 4 and 5. The increase in weight should be almost entirely confined to 4. When 5 begins to show notable increase in weight, 4 should be freshly charged.

After 10 minutes boiling the heat is turned off, but aspiration is continued for 20 minutes longer.

The decomposition flask may be charged with the sample and the water added through a funnel tube reaching nearly to the bottom of the flask; or, more conveniently by first charging with water, and dropping in the sample, wrapped in tissue paper, immediately replacing the rubber cork which carries the funnel tube and the exit tube.

The air aspirated through the apparatus may be freed from carbon dioxide by a soda lime tube, above the funnel tube. This precaution is not usually necessary, the error due to atmospheric

carbon dioxide being so small as to be negligible. It is also desirable to have an absorption bottle immediately before the suction tube in order to observe conveniently the rate of the air current. A negative pressure must be maintained during the whole operation but the rate of flow of air should not exceed three bubbles per second.

D. *Determination of Water-Soluble Extractive in Tea*

A fair sample of the dry tea is powdered so as to pass through a sieve of $\frac{1}{3}$-inch mesh. Two and one-half grams of the powdered tea is treated with 225 cc. cold, distilled water in a glass flask of about 500 cc. capacity, fitted with a cork and glass tube of about 25 inches length and $\frac{1}{2}$ inch diameter, or with a reflux condenser. The flask is rapidly heated until the water boils, and boiling is continued for one hour.

The whole contents are transferred to a 250cc. flask and made up to the mark at about 70°C. A filtrate of 50 cc. (filtered hot) representing 0·5 gram of dried sample is evaporated to dryness, and weighed.

DIVISION II

(NOTE:—*For the purposes of these regulations the terms millilitre (ml.) and cubic centimetre (cc.) shall be synonymous.).*

A. REGULATIONS for Fixing Standards of Quality and Potency, and Defining Official Methods of Biological Testing of Drugs Mentioned or Described in parts I and II of Schedule B of the Food and Drugs Act, R.S. 1927.

GENERAL REQUIREMENTS

Labelling.

1. The following items shall appear on the labels of packages and immediate containers:

(1) Name of manufacturer.
(2) Address of manufacturer.
(3) Proper name of the product as specified in these regulations.
(4) Potency of product.
(5) Lot number.
(6) Expiration date.

TINCTURE OF DIGITALIS

Definition

1. Tincture of Digitalis shall be the alcoholic extract prepared from the leaves of *Digitalis purpurea,* Linné, which preferably shall have been previously extracted with purified petroleum benzine.

Standard

2. The standard preparation shall be that kept in the Laboratory of Hygiene, Department of Pensions and National Health, Ottawa, where portions for comparative testing may be obtained on application.

Potency

3. Tincture of Digitalis shall be of such potency that the specific activity of one ml. corresponds to that of one International Unit.

4. The method used for preparing the extract from the standard preparation and for its use in a comparative biological test, and the biological method employed in making the test, shall be that employed in the Laboratory of Hygiene, details of which may be obtained on application to the Chief, Laboratory of Hygiene, Department of Pensions and National Health, Ottawa.

Quality

5. The concentration of the alcohol in the tincture of digitalis shall be not less than 70 per cent by volume.

Labelling

6. See General Requirements, 1, Page 51.

7. The labels on the package and the container shall state that each ml. contains one International Unit.

Expiration Date

8. The expiration date shall be twelve months after assay.

PRODUCTS MADE FROM DIGITALIS OTHER THAN THE TINCTURE

Potency

1. The potency of the preparation shall be expressed in International Units.

Labelling

2. See General Requirements, 1, Page 51.

TINCTURE OF STROPHANTHUS

Definition

1. Tincture of Strophanthus shall be the alcoholic extract prepared from the seeds of *Strophanthus kombé,* Oliver, or *Strophanthus hispidus,* De Candolle, which shall have previously been extracted with purified petroleum benzine.

Standard

2. The standard preparation shall be that kept in the Laboratory of Hygiene, Department of Pensions and National Health, Ottawa, where portions for comparative testing may be obtained on application.

Potency

3. Tincture of Strophanthus shall be of such potency that the specific activity of one ml. corresponds to that of 4·2 mgm. Canadian Standard ouabain as determined by biological test.

4. The biological method employed in making the test shall be that employed in the Laboratory of Hygiene, details of which may be obtained on application to the Chief, Laboratory of Hygiene, Department of Pensions and National Health, Ottawa.

Quality

5. The concentration of the alcohol in the Tincture of Strophanthus shall be not less than 88 per cent by volume.

Labelling

6. See General Requirements, 1, Page 51.

Expiration Date

7. The expiration date shall be two years after assay.

PRODUCTS MADE FROM STROPHANTHUS OTHER THAN THE TINCTURE

Potency

1. The potency of the preparation shall be expressed in terms of the tincture equivalent.

Labelling

2. See General Requirements, 1, Page 51.

LIQUID EXTRACT OF ERGOT

Definition

1. Liquid Extract of Ergot shall be the acid alcoholic extract prepared from the dried sclerotium of *Claviceps purpurea* (Fries) Tulasne, developed on rye plants. The powdered ergot shall first be extracted with purified petroleum benzine.

Standard.

2. The standard preparation shall be that kept in the Laboratory of Hygiene, Department of Pensions and National Health, Ottawa, where portions for comparative testing may be obtained on application.

Potency.

3. The potency of Liquid Extract of Ergot for the purpose of these regulations shall be equal to the specific activity corresponding to the standard preparation when tested biologically.

4. The method used in carrying out the biological test shall be that employed in the Laboratory of Hygiene, details of which may be obtained on application to the Chief, Laboratory of Hygiene, Department of Pensions and National Health, Ottawa.

Quality.

5. The alcoholic content of the finished liquid extract shall be not less than 50 per cent by volume.

Labelling.

6. See General Requirements, 1, Page 51.

Expiration Date.

7. The expiration date shall be twelve months after assay.

PRODUCTS MADE FROM ERGOT OTHER THAN THE LIQUID EXTRACT

1. The potency of the preparation shall be expressed in terms of the liquid extract equivalent.

Labelling.

2. See General Requirements, 1, Page 51.

THYROID

1. Thyroid shall be the cleaned, defatted, dried, powdered thyroid glands of domestic animals used for food. The proper name of the preparation shall be "Thyroid".

Quality.

2. Thyroid shall contain no added iodine in either inorganic or organic form; the iodine present being in the naturally occurring thyroid combination.

3. Thyroid shall have an iodine content of 0·3 per cent; the deviation to be not greater than 0·03 per cent either in excess or deficiency.

4. The method used in carrying out the test shall be that employed in the Laboratory of Hygiene, details of which may be obtained on application to the Chief, Laboratory of Hygiene, Department of Pensions and National Health, Ottawa.

Labelling.

5. See General Requirements, 1, Page 51.

B. Regulations for the Licensing, Manufacture and Sale of Drugs listed in Parts II and III, Schedule B of the Food and Drugs Act, R.S. 1927; hereinafter referred to as Biological Products.

General Requirements

1. *Licences*:

1. An establishment shall be subject to licence for the manufacture of one or more of its products when these are held by the Deputy Minister of Pensions and National Health to be either a virus, serum, toxin, antitoxin, a preparation of pituitrin or any other animal tissue preparation, or a product analogous thereto, and of established value in the prevention or treatment of diseases of man, and intended for parenteral administration.

2. Application for licences shall be made to the Deputy Minister of Pensions and National Health, Canada, at Ottawa, according to a prescribed form, as follows:—

Form of Application for a Licence (*) for Manufacture of Drugs mentioned or described in Parts II and III, Schedule B, Food and Drugs Act, R.S. 1927.

To the Deputy Minister of Pensions and National Health, Ottawa, Canada.

I,
We, of ,
hereby apply for a licence (*) to manufacture at , the undermentioned biological products for sale:—

.. ..
.. ..
.. ..
.. ..
.. ..
.. ..

and I undertake to comply with all requirements of
We
the Food and Drugs Act, R.S., 1927, and the Regulations made thereunder.

The names and qualifications of the expert staff responsible for the manufacture or testing of the above-mentioned products are as follows:—

Names Qualifications

Signature.. .. ..

Date.. .. ..

3. This application is to be accompanied by a fee of ten dollars, by cheque or order, payable to the Receiver General of Canada.

4. Licences so issued will continue in force for twelve months dating from April first of any year, unless suspended or revoked for cause.

5. Applicants for licences, who already hold a licence issued by the Department of Government of their own or any other country which exercises supervision and licensing of an establishment manufacturing the drugs mentioned in Part II and III, Schedule B of this Act, may at the discretion of the Deputy Minister of Pensions and National Health, be allowed licence without further inspection.

(*) If not resident in Canada, applicants should specify whether they already hold a licence issued by their own government, and, if so, should give all details, including an official copy of the licence held.

6. Licences shall be issued, and may be suspended, or revoked by the Deputy Minister of Pensions and National Health.

7. Licences shall be issued only after inspection of establishments and examination of the products for which the licence is desired. In the case of establishments already licensed, licences for new products may, at the discretion of the Deputy Minister of Pensions and National Health, be granted without re-inspection of the establishment.

8. The following form of licence is prescribed:—

This is to certify that.....
of.....is (are) hereby authorized under the provisions of the Food and Drug Act, R.S. 1927, to engage in the manufacture of the following drugs mentioned or described in Parts II and III, Schedule B of the said Act

.....
.....
.....
.....

and of only such as have been so specified, and for which licence has not been suspended or revoked. This expires on March 31, 19....

(Signed).....
Deputy Minister.

9. At the discretion of the Deputy Minister of Pensions and National Health, licences may not be reissued without inspection of the establishments and laboratory examination of the products. The inspection and laboratory reports shall be passed upon by the Deputy Minister of Pensions and National Health.

10. Should important changes in personnel, method, equipment, or location be made by an establishment holding licence, the manufacturer shall immediately notify the Deputy Minister of Pensions and National Health.

11. For the purpose of these regulations, viruses, serums, toxins, antitoxins, and analogous products intended for use by parenteral administration and applicable to the prevention or treatment of diseases of man, shall be referred to as biological products and defined as follows:

I. A virus shall be a product containing the minute living cause of an infectious disease.

II. A serum shall be the product obtained from the blood of an animal by removing the clot or clot components and the blood cells.

III. A toxin shall be a product containing a soluble substance poisonous to laboratory animals or to man in doses of one millilitre or less of the product, and having the property, following the injection of nonfatal doses into an animal, of producing therein another soluble substance which specifically neutralizes the poisonous substance and which shall be demonstrable in the serum of the animal thus immunized.

IV. An antitoxin shall be a product containing the soluble substance in the serum or other body fluid of an immunized animal which specifically neutralizes the toxin against which the animal shall be immune.

V. A product shall be analogous (a) to a virus if prepared from a virus, including micro-organisms actually or potentially virulent; (b) to a serum, if prepared from some protein constituent of the blood and intended for parenteral administration; (c) to a toxin or antitoxin, if intended, by parenteral administration, for the prevention or treatment of disease through specific immunization.

II. *Inspection:*

12. Inspections for original licence of an establishment shall not be made until assurances are received that the establishment is in running order and prepared to manufacture the complete product for which licence is desired. A fixed fee for inspection shall be ten dollars; and, in addition, there shall be charged the daily living and travelling expenses of the Inspector.

13. The inspection shall be made by an Inspector or a Board of Inspectors detailed by the Deputy Minister of Pensions and National Health.

14. Inspection shall be unannounced unless special circumstances render this undesirable.

15. It shall be the duty of the Inspector to call upon the acting head of the establishment stating the object of his visit.

16. The Inspectors shall be authorized to examine all portions of the premises, appliances, stables, barns, warehouses, records, the methods employed in actual operation, and enquire into the professional

standing of all technically employed and shall investigate fully the methods of preparation, storing, dispensing and other details in the manufacture and sale of drugs mentioned or described in Parts II and III, Schedule B, Food and Drugs Act, R.S. 1927.

17. The Inspectors shall be authorized to examine carefully into location, construction, or administration of establishments which would tend to endanger the potency or purity of the products.

18. In case faulty methods of preparation, faulty location, faulty construction, or faulty administration of licensed establishments are observed during inspection, the Inspectors shall bring the same to the attention of the manufacturer and shall forward a report of the conditions found, together with their recommendations, to the Deputy Minister of Pensions and National Health.

19. Should the faulty conditions discovered during inspection, or upon laboratory tests, be found upon review by the Deputy Minister of Pensions and National Health, to be of sufficient importance, the licence of the establishment may be cancelled or suspended. In case of suspension, if the said faulty conditions are not corrected within 60 days, the said licence shall be revoked.

20. In case licence is refused following inspection, re-inspection shall not be ordered until assurances have been received that the establishment affected has corrected all the faulty conditions which were made the basis for the previous refusal of a licence.

21. The fact of suspension or revocation of licence, with causes therefor, may be published in the *Canada Gazette* by the Deputy Minister of Pensions and National Health.

22. The organization of licensed establishments shall be such that the responsible head is actually in permanent control of the buildings, ground, equipment and personnel; and good discipline shall prevail.

23. In considering the licence of an establishment, regard shall be had to the training and competence of the technical workers concerned.

24. Permanent record shall be kept with date, of the various steps in the manufacture, testing, dis-

position and distribution of each lot, so that at any time these steps may be traced by the Inspector as regards any lot number.

25. Laboratory cultures and other materials used in the production of biological products shall be labelled and preserved in a safe, orderly manner. An Inspector may demand and select and shall have handed to him subcultures, samples of other materials so used in the production of biological products, as well as samples of the finished products, for examination by the Laboratory of Hygiene of the Department of Pensions and National Health, Ottawa.

26. All work with spore-bearing, pathogenic micro-organisms shall be so separated from other work, and the containers permanently so marked as to avoid the possibility of contamination of products.

27. Laboratory procedures of a diagnostic nature shall, if conducted in a licensed establishment, be entirely separate from those for the production of biological products.

28. Laboratories for the production of biological products shall be efficiently screened during the fly season.

29. Sterilization and subsequent handling of containers, filling apparatus and other materials which may come in contact with biological products during manufacture, shall be such as to ensure the absence of living bacterial spores; except that the concentration of antitoxins may be conducted with scrupulous cleanliness rather than with absolute sterility.

30. For sterility tests on biological products see Appendix A.

31. Records of the date, duration and temperature of each sterilization shall be kept. Such records shall be made by means of automatic registration devices, or by the personnel of the sterilizing room.

32. Details of sanitary standards, methods of testing, and methods of keeping records, may be communicated to manufacturers by Inspectors.

33. All containers used in the preparation of biological products shall be of such construction as will readily permit inspection for cleanliness.

34. The construction of bleeding rooms and rooms for vaccine animals shall be such as to permit a thorough hosing down and cleaning.

35. Hot water shall be provided in bleeding rooms and vaccine stables.

36. Stable floors shall be so constructed and cared for as to ensure cleanliness, and stables shall be well lighted and well ventilated.

37. No manure, rubbish, or other refuse shall be so stored as to permit the breeding of flies on the premises of any licensed establishment.

38. All personnel, animals and equipment used in the production of hog cholera serum, and all other veterinary products, shall be kept entirely separate from personnel, animals and materials used in the production of biological products for human use.

39. Animals used in the production of biological products shall be kept under competent daily inspection and preliminary quarantine by the establishment for a period of at least seven days before use. Only healthy animals, free from communicable diseases shall be used; during the quarantine period those of the equine genus must be shown to be free from glanders, and those of the bovine genus must be shown to be free from tuberculosis.

40. All horses used in the production of biological products, except those horses which are actively immune to tetanus, shall be given no less than 500 units of tetanus antitoxin semi-monthly, or 2,000 units monthly, or a correspondingly effective amount of tetanus anatoxin (toxoid).

41. Necropsy records shall be kept of all animals which die, or are killed, after having been used in the production of biological products.

42. In cases of actual or suspected extraneous infection with foot-and-mouth disease, glanders, tetanus, anthrax, gas-gangrene, or " black-leg " among animals used for the production of biological products, the manufacturer shall immediately notify the Deputy Minister of Pensions and National Health.

43. Animals used for propagation of vaccine virus shall be thoroughly cleansed with soap and water at the beginning of quarantine and at its conclusion. No part of the animal shall be vaccinated which is readily liable to be contaminated by faeces.

44. Each year, at least four of the animals used in propagating vaccine virus of any one strain, shall be kept for a period of two weeks subsequent to the removal of the virus, and observed sufficiently to demonstrate the absence of foot-and-mouth disease, if such observation be deemed necessary by the Deputy Minister of Pensions and National Health. At the termination of the period of observation in the case of these four animals, and within 48 hours after taking the vaccine virus in the case of all other animals, a necropsy shall be made upon each animal and permanent records kept of each necropsy in which particular note shall be made of biological changes.

45. All vaccine material from any animal having, or suspected of having a communicable disease other than vaccinia, shall be destroyed.

46. No animals used for the purpose of propagating vaccine virus shall be removed from the establishment prior to necropsy.

47. The personnel who care for the vaccine animals shall be excluded from horse stables and paddocks, and from contact with horses while vaccine is being propagated.

48. Extraneous materials shall not be stored or permitted in or about vaccine stables or operating rooms.

49. The preparation by licensed establishments of vaccine virus on, or with, "points" is prohibited. Vaccine virus shall be furnished only in glass capillary tubes or in other glass containers. This shall not prohibit the enclosure in the same package, but separate from the virus, of a metal or glass instrument for inserting the virus.

50. Capillary tubes for vaccine virus shall be filled mechanically in vacuum jars, and prior to filling shall be sterilized in the same containers which are used for filling.

III. *Labelling:* (Sect. 3 (*b*), Food and Drugs Act, R.S. 1927.

51. In labelling products manufactured under licence, the proper name of each product shall be that specified in the licence and in the case of products not manufactured under licence the commonly accepted names thereof.

52. The proper name of each product must appear prominently upon the label in easily legible type.

53. In the case of products prepared by methods other than the usual or standard methods, the proper name used to designate the product in the licence and on the labels shall be sufficiently descriptive to indicate such deviation. Should the species of animal used differ from that usually or originally employed, the name of the species shall be included as part of the proper name on the label.

54. In the case of products for which an official standard of potency has been adopted, the potency shall be expressed on the label in terms of the official standard.

55. Each package shall be marked with the date (the "expiration date") after which the contents cannot be expected beyond reasonable doubt to yield their specific results.

56. The *date of manufacture* shall be as follows:—

(1) For products for which an official standard of potency exists, the last date of satisfactorily passing a potency test;

(2) For products for which no official standard of potency exists, the date of removal from the animal, in case of animal products, or the date of cessation of growth in the case of other products; or

(3) In the case of animal or vegetable extracts, the date of extraction.

57. The *date of issue* of products from cold storage shall be accepted in lieu of the date of manufacture, provided this date of issue is not more than two years after the date of manufacture, if the product is kept constantly below 0° C.; or not more than one year after the date of manufacture, if the product is kept constantly below 5° C.; or not more than six months after the date of manufacture, if the product is kept constantly at a temperature not exceeding 10° C.; or not more than three months

after date of manufacture, if the product is kept constantly below 15° C.

58. Tests for potency, if applicable, shall be made after the completion of all the processes of manufacture, except filling the final containers.

59. The following items shall appear on the labels of unwrapped containers as specified below:—

(1) Name of manufacturer.
(2) Address of manufacturer.
(3) Licence number (only if the product is manufactured under licence).
(4) Proper name of the product (see Sections 51 and 52).
(5) Potency of product.
(6) Lot number.
(7) Expiration date.
(8) Preservative, name and amount.

A. On the outside labels or wrappers of the packaged containers:—items 1-8 inclusive.

B. On the labels of inner containers containing more than one dose:—items 1, 4, 5, 6 and 7.

C. On the labels of inner containers containing not more than one dose:—items 1, 4 and 6; on syringe containers, item 5 shall also appear.

60. In case a product manufactured by a licensed establishment is sold by another establishment, the name, address, licence number and lot number of the original manufacturer shall appear plainly on the label, and the name of the second establishment may appear on the label as the selling agent. In case any part of the process, such as finishing and bottling, is performed by the second establishment, this establishment also must hold a licence for the manufacture of the product; the names, addresses and licence numbers of both establishments must appear on the label, and the records of both establishments shall show plainly the degree of responsibility of each in the process of manufacture.

IV.—*Examination of Products:*

61, Licensed establishments shall furnish to the Inspector or on request, shall send to the Laboratory of Hygiene of the Department of Pensions and National Health, Ottawa, adequate samples of products for examination.

62. Samples of special lots of products, or of all lots of particular products, may be required to be sent to the Laboratory of Hygiene of the Department of Pensions and National Health, Ottawa, for examination prior to being offered for sale or sold.

63. In examining biological products, consideration shall be given to the care and safety of containers, and to those materials accompanying them which are intended to facilitate administration of their contents.

64. Standard samples for comparison of products may be distributed by the Laboratory of Hygiene, and may be obtained on application to the Chief of the Laboratory of Hygiene.

65. No liquid serum shall contain more than 20 per cent total solids, nor more than 0·5 per cent of phenolic preservative.

66. Products intended to be used intraspinally or intravenously shall be clear, free from excessive colouration, or excessive viscosity; and those to be used intraspinally shall contain not more than 0·35 per cent of phenolic preservative.

67. Containers of products intended to be used intraspinally, or intravenously, shall be of such material that the presence of objectionable colour or of sediment in the contents may be detected.

68. Upon the discovery of lack of purity or potency of any product of a licensed establishment, the fact shall be communicated immediately to the manufacturer, who shall withdraw the product from the market without delay.

V.—*Import Shipments*:

69. Every import shipment of drugs mentioned or described in Part IV of Schedule B shall be accompanied by two sample packages of each lot number contained in the shipment; and said samples shall be forwarded by the Collector of Customs at the port of entry to the Laboratory of Hygiene of the Department of Pensions and National Health, Ottawa, for examination. If separate samples are not found accompanying the shipment, samples shall be obtained from the shipment by the Collector of Customs and forwarded to the Laboratory of Hygiene of the Department of Pensions and National Health, Ottawa.

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Specific Requirements

pituitary extract (posterior lobe)

Definition

1. Pituitary extract (posterior lobe) shall be the aqueous extract prepared from the separated posterior lobe of the pituitary body. The proper name of this product shall be "Pituitary Extract (posterior lobe)."

Standard

2. The standard preparation shall be that kept in the Laboratory of Hygiene, Department of Pensions and National Health, Ottawa, where portions for comparative testing may be had upon application.

Potency

3. The unit of pituitary extract for the purpose of these regulations shall be the International Unit.

4. The method used for preparing the extract from the standard preparation, and for its use in a comparative biological test, and the biological method employed in making the test, shall be that employed in the Laboratory of Hygiene, details of which may be obtained on application to the Chief, Laboratory of Hygiene, Department of Pensions and National Health, Ottawa.

Quality

5. The solution shall be sterile.

6. The acidity of the prepared aqueous extract shall be such that the hydrogen-ion concentration is not less than that corresponding to pH 4, nor greater than that corresponding to pH 3.

7. The glass of the container shall be clear, non-alkaline, resistance glass.

Labelling

8. See Section 59.

9. The potency shall be expressed in International Units per ml.

Expiration Date

10. The expiration date shall be eighteen months after assay.

EPINEPHRINE.—EPINEPHRINE HYDROCHLORIDE SOLUTION

Definition

1. (*a*) Epinephrine shall be laevo-methylaminoethanolcatechol. The proper name of the preparation shall be "Epinephrine."

(*b*) Epinephrine Hydrochloride Solution shall be a solution of epinephrine in water and hydrochloric acid containing not less than 0·095 per cent and not more than 0·105 per cent of epinephrine. The proper name of the preparation shall be "Epinephrine Hydrochloride Solution."

Standard

2. The standard preparation shall be that kept in the Laboratory of Hygiene, Department of Pensions and National Health, Ottawa, where portions for comparative testing may be had upon application.

Potency

3. The potency of epinephrine hydrochloride solution shall be the specific activity corresponding to that of a solution of one gram of the standard preparation dissolved in one litre of distilled water, with the minimum quantity of hydrochloric acid necessary to make the hydrochloride.

4. The method used in carrying out the biological test shall be that employed in the Laboratory of Hygiene, details of which may be obtained on application to the Chief, Laboratory of Hygiene, Department of Pensions and National Health, Ottawa.

Quality

5. The solution shall be sterile.

6. The solution shall be put up in clear glass containers, protected from light.

7. The solution shall be free from precipitate and from any marked brown colouration.

Labelling

8. See Section 59.

Expiration Date

9. The expiration date shall be eighteen months after assay.

PROVISIONS APPLICABLE TO DIPHTHERIA ANTITOXIN

Definition

1. Diphtheria antitoxin shall be the serum, or the antitoxic globulins, separated from the blood of horses or other equidae which have been immunized against diphtheria toxin. The proper name of the substance shall be "Diphtheria Antitoxin."

Potency

2. Diphtheria antitoxin having a potency of less than 350 units per ml. in the case of liquid preparations, or less than 4,000 units per gram in the case of dried preparations, shall not be issued, unless the label on the container bears the notice "not to be used in the treatment of diphtheria."

3. The unit of diphtheria antitoxin for the purposes of these regulations shall be the quantity contained in such an amount of a standard preparation exactly equivalent to the unit accepted for international use and based upon the unit originally established by Ehrlich.

4. The potency in units of diphtheria antitoxin shall be determined in accordance with an approved method as established by the National Institute of Health (formerly the Hygienic Laboratory), U.S. Public Health Service, as described in their Bulletin No. 21, 1905, by the subcutaneous injection into guinea pigs of a mixture consisting of the antitoxin under test and of a diphtheria toxin which has been standardized in relation to the standard preparation.

Quality

5. (1) Diphtheria antitoxin shall be issued for therapeutic and prophylactic use in the form of either—

(*a*) the serum separated from the blood or plasma of animals immunized against diphtheria toxin; or

(*b*) the solution of the globulins containing the specific antitoxin; or

(*c*) a dry powder prepared from (i) the natural serum, or (ii) the antitoxic globulins containing no antiseptic or other added substance.

(2) If issued in fluid form the liquid at the time of issue shall be clear or shall show, at most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of de-

cantation of the coagulated blood without any addition other than antiseptic, or subtraction) shall not contain more than 10 per cent of solid matter. A solution of the separated antitoxin globulins shall not contain more than 0·1 gram of solid matter for each 500 antitoxin units.

Labelling

6. See Section 59.

Expiration Date

7. The expiration date shall be one year after date of manufacture (see Sections 56 and 57), with a 20 per cent excess of potency; two years after with a 30 per cent excess; three years with a 40 per cent excess; or four years with a 50 per cent excess.

PROVISIONS APPLICABLE TO THE REAGENTS USED IN THE SCHICK TEST FOR THE DIAGNOSIS OF SUSCEPTIBILITY TO DIPHTHERIA

Definition

1. The reagents used in the Schick Test shall be "Diphtheria Toxin" and "Schick Control."

(i) The Diphtheria Toxin shall be a sterile filtrate from a culture in nutrient broth of the specific organism of diphtheria (*Corynebacterium diphtheriæ*). It shall be supplied undiluted (except as hereinafter provided), accompanied by a container in the same box or carton holding such a volume of sterile saline solution as when mixed with the accompanied quantity of the undiluted toxin, will make a dilution of the strength appropriate for use in the test. The proper name of this substance shall be "Diphtheria Toxin for Schick Test (undiluted)."

(ii) The Schick Control shall be prepared either from (*a*) the same batch of the Diphtheria Toxin as that with which it is issued for sale, by destroying the specific toxicity by heating the toxin to 95° C. for five minutes; or (*b*) Toxoid (Anatoxine Ramon) suitably diluted with sterile saline. The proper name of this substance shall be "Schick Control."

(iii) When "Diphtheria Toxin for Schick Test (undiluted)" and "Schick Control" are packaged together, the proper name shall be "Diphtheria Toxin for Schick Test with Control."

2. Reagents for the Schick Test may be prepared by methods other than those indicated in these sections, including dilution with the use of previously sterilized stabilizers, provided that the finished product shall conform to the regulations, and be appropriately labelled.

Potency

3. (i) The minimal lethal dose (M.L.D.) of Diphtheria Toxin for the purpose of this test shall be the smallest amount of toxin which, when diluted to a volume of 4 ml. and injected subcutaneously into guinea pigs weighing from 250 to 280 grams, causes death in less than 96 hours in 75 per cent of the guinea pigs, with lesions typical of uncomplicated diphtheria poisoning

(ii) The human test dose is determined by:—

Intracutaneous injection into normal guinea pigs in mixtures with different proportions of diphtheria antitoxin; one test dose mixed with 1/750 or more of a unit of antitoxin must cause no local reaction, but mixed with 1/1,250 or less of a unit of antitoxin must cause a definite local reaction of the type known as the "positive Schick reaction";

And by intracutaneous injection into normal guinea pigs, without admixture with antitoxin; 1/50 of one test dose must not cause, and 1/25 of one test dose must cause, a definite local reaction of the type known as the "positive Schick reaction."

(iii) In packaging the "Diphtheria Toxin for Schick Test (undiluted)", the following specifications shall apply:—

Total number of human test doses per package..	..10 to 100
Amount of toxin per human test dose, and volume of human dose, diluted.	..1/50 M.L.D. in 0·1 ml., or 1/40 M.L.D. in 0·2 ml.
Volume of undiluted toxin..	Not over 0·2 ml. per M.L.D.

(iv) The reagent for the Schick Control shall be tested by intracutaneous injection into guinea pigs and shall give the negative Schick reaction.

Quality

4. (i) Samples for testing, preliminary to distribution, shall be taken at random from each lot and shall be sufficient in number to include at least 20 M.L.Ds. with sufficient regularly filled diluent vials for diluting the entire amount for human use.

(ii) A safety test shall be carried out on each lot of the filled Schick Test Toxin by injecting 5 ml. amounts into the flank of each of two guinea pigs, followed by the injection of about 80 units of diphtheria antitoxin into the opposite flank of the animals. The animals must remain normal for at least ten days.

Labelling

5. In addition to general requirements of labelling (see Section 59), the label on the diphtheria toxin container shall state the number of human test doses contained; the label for diluent container shall also state the volume of the diluted dose to be used, and the outfit shall contain adequate directions for diluting and mixing. When a stabilizer is used the name thereof shall appear on the labels. In printing labels for the undiluted diphtheria toxin the words "Diphtheria Toxin" shall appear in type *larger* than any other type used on the label. The label on the package shall bear a warning that the product shall be stored in a refrigerator at a temperature not above 5° C. (41° F.).

Expiration Date

6. The expiration date shall be six months after date of manufacture (see Section 56). For diluted, stabilized toxin the expiration date shall be nine months after date of manufacture.

PROVISIONS APPLICABLE TO DIPHTHERIA TOXOID

Definition

1. Diphtheria Toxoid (Anatoxine Ramon), shall be sterile, formalized, detoxified, diphtheria toxin. The proper name of this preparation shall be "Diphtheria Toxoid," ('Anatoxine Ramon').

Quality

2. (i) Diphtheria Toxoid shall be prepared from a culture in nutrient broth of the specific organism of diphtheria (*Corynebacterium diphtheriæ*) and shall be made by effecting a sterile filtration of the culture on or about the seventh day after inoculation, which shall contain at least 500 M.L.Ds., (see item 3 (i), provisions applicable to the reagents used in the Schick test), of toxin per ml, and 12 L.Fs per ml., and acted upon by the addition of not more than 0·18 per cent of formaldehyde to the filtrate; the whole to be heated at 37°C. until detoxification is complete.

(ii) *Primary Toxicity Test*: Each lot of toxoid shall be tested for toxicity by injecting 5 ml. amounts subcutaneously into each of not less than ten guinea pigs (300–400 grams weight); at least two guinea pigs shall be injected from each bulk container of toxoid; at least sixty per cent of the animals must remain normal for one month; at least one animal injected from each bulk container must survive; no local or general symptoms or death shall be attributable to diphtheria toxin.

(iii) *Antigenic Test*: After passing the primary toxicity test, each lot shall be tested for antigenic properties by injecting 0·5 ml. amounts into each of six guinea pigs (350 to 400 grams weight). At the end of four weeks the animals shall be Schick tested and two weeks later, following the reading of the Schick test, 5 M.L.D. of diphtheria toxin shall be injected subcutaneously into each animal. At least four of the animals must survive.

(iv) *Final Toxicity Test*: The toxoid shall be filled aseptically (without or with the addition of not more than 0·1 per cent of phenol), into clear glass containers sealed by fusion. Each lot shall then be tested for final toxicity by injecting intracutaneously into guinea pigs $\frac{1}{10}$ ml. of the undiluted toxoid and $\frac{1}{10}$ ml. of a one in ten dilution. The undiluted material must show a zone of reaction not greater than 12mm. (approximately), whilst the one in ten dilution of the toxoid must show a zone of reaction not greater than 5 mm. (approximately).

In addition, two guinea pigs shall be injected subcutaneously, each with 5 ml. of toxoid from each

lot of final containers. These animals must survive for ten days without exhibiting any symptoms of diphtheria poisoning.

Labelling

3. In addition to the general requirements of labelling (see Section 59), the appropriate dose for purposes of immunization shall be stated on the labels.

Expiration Date

4. The expiration date shall be two years after date of manufacture (see Sections 56 and 57).

PROVISIONS APPLICABLE TO DIPHTHERIA TOXIN-ANTITOXIN MIXTURE

Definition

1. Diphtheria Toxin-Antitoxin Mixture shall be diphtheria toxin (the sterile filtrate from a culture in nutrient broth of *Corynebacterium diphtheriae*), the specific toxicity of which has been reduced to a low value by the addition of diphtheria antitoxin, in such a manner that it shall retain efficient properties as an immunizing antigen. Its proper name shall be "Diphtheria Toxin-Antitoxin Mixture."

Quality and Potency

2. Diphtheria Toxin-Antitoxin Mixture shall be tested to determine (*a*) that the specific toxicity of the toxin used in its preparation has been so reduced that it does not exceed the prescribed maximum, and (*b*) that it retains adequate potency as an immunizing antigen:—

(i) Tests for reduction of toxicity so as not to exceed the prescribed maximum.—(*a*) Five human doses of the Diphtheria Toxin-Antitoxin Mixture under test shall be injected into each of five normal guinea pigs each weighing 250 to 350 grams. This injection must not cause the death of any of the guinea pigs within six days following the injection. (*b*) If any of the guinea pigs injected die after the sixth day from the specific toxaemia, one human dose of the Diphtheria Toxin-Antitoxin Mixture under test shall be injected into each of five normal guinea pigs each weighing 250 to 350 grams. This injection must not

cause the death of any of the guinea pigs within 30 days following the injection.

If a batch of Diphtheria Toxin-Antitoxin Mixture is shown by either of these tests to have a greater toxicity than the maximum hereby indicated, it shall not be issued unless and until the toxicity has been so reduced by further treatment that it does not exceed that maximum.

(ii) Test for potency as an immunizing antigen. —A Quantity of the Diphtheria Toxin-Antitoxin Mixture not exceeding five human doses shall be injected into each of five normal guinea pigs, which shall be tested for immunity to Diphtheria Toxin at a date not later than six weeks after this injection. The test for immunity may be made by either of the two following methods:—

(*a*) The test may be made by intracutaneous injection into each guinea pig of one test dose of Schick Toxin. If more than two out of the five guinea pigs exhibit a positive Schick reaction, the batch of Diphtheria Toxin-Antitoxin Mixture shall be treated as insufficiently potent, and shall not be issued; or

(*b*) the test may be made by subcutaneous injection into each guinea pig of five minimum lethal doses of diphtheria toxin. If more than two out of the five guinea pigs die as a result of this injection the batch of Diphtheria Toxin-Antitoxin Mixture shall be treated as insufficiently potent, and shall not be issued.

Labelling

3. In addition to the requirements specified in Section 59, the label on the container shall bear a statement of the dose (hereinafter referred to as the "human dose"), appropriate for administration at one injection to a human subject.

Expiration Date

4. The expiration date shall be six months after date of manufacture (see Sections 56 and 57).

PROVISIONS APPLICABLE TO TETANUS ANTITOXIN

Definition

1. Tetanus antitoxin shall be the serum, or the antitoxic globulins, separated from the blood of horses or other equidae which have been immunized against tetanus toxin. The proper name of the substance shall be "Tetanus Antitoxin."

Potency

2. Tetanus antitoxin having a potency of less than 300 units per ml. in the case of liquid preparations, or less than 2,400 units per gram in the case of dried preparations, shall not be issued.

Tetanus antitoxin having a potency of less than 800 units per ml. in the case of liquid preparations, or less than 8,000 units per gram in the case of dried preparations, shall not be issued for the treatment of tetanus.

3. The unit of tetanus antitoxin for the purposes of the regulations shall be that distributed by the National Institute of Health (formerly the Hygienic Laboratory), U.S. Public Health Service, as described in their Bulletin No. 43, 1908.

4. The potency in units of tetanus antitoxin shall be determined by the subcutaneous injection into guinea pigs of mixtures of the preparation with a tetanus toxin, which has been standardized in relation to the standard preparation of tetanus antitoxin. The neutralizing value may be determined by observation either—

(*a*) of the greatest dose which just fails to protect a guinea pig from death within 4 days, or

(*b*) of the least dose which just suffices to protect a guinea pig from the appearance of symptoms of tetanus.

Quality

5. (1) Tetanus antitoxin shall be issued for therapeutic and prophylactic use in the form of either—

(*a*) the serum separated from the blood or plasma of animals immunized against tetanus toxin; or

(*b*) a dry powder prepared from (i) the natural serum, or (ii) the antitoxic globulins, containing no antiseptic or other added substance.

(2) If issued in fluid form the liquid at the time of issue shall be clear, or show at most a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood without any addition other than antiseptic, or subtraction) shall not contain more than 10 per cent of total solid matter. A solution of the separated antitoxic globulins shall not contain more than 0·1 gram of solid matter for each 300 antitoxin units.

Labelling

6. See Section 59.

Expiration Date

7. The expiration date shall be one year after date of manufacture (see Section 56), with a 20 per cent excess of potency; two years after with a 30 per cent excess; three years with a 40 per cent excess; or four years with a 50 per cent excess.

PROVISIONS APPLICABLE TO TETANUS TOXOID

Definition

1. Tetanus toxoid shall be sterile, formalized, detoxified, tetanus toxin. The proper name of this preparation shall be "Tetanus Toxoid."

Quality

2. Tetanus toxoid shall be prepared from a culture in nutrient broth of the specific organism of tetanus (*Clostridium tetani*) and shall be made by obtaining on or about the fourteenth day after inoculation a sterile filtrate of the culture, which shall contain at least 10,000 M.L.D. of toxin per ml., and shall be acted upon by the addition of formaldehyde to the filtrate.

3. All procedures in the preparation of tetanus toxoid shall be kept entirely and completely separate from all other biological products until the toxoid has been finally filtered and thoroughly tested for sterility (see Section 26).

4. Before engaging in the manufacture of this product, a manufacturer shall apply to the Deputy Minister of the Department of Pensions and National Health for inspection, and shall place before him for consideration the technique to be employed,

complete in all details. Furthermore, before any lot is released for distribution, a manufacturer shall submit to the Deputy Minister protocols covering sterility tests, toxicity tests and antigenic tests, together with other relevant data.

Labelling

5. In addition to the general requirements of labelling (see Section 59), the appropriate dose for purposes of immunization shall be stated on the labels.

Expiration Date

6. The expiration date shall be eighteen months after date of manufacture (see Sections 56 and 57).

PROVISIONS APPLICABLE TO ANTI-SERUMS FOR WHICH NO STANDARDS OF POTENCY ARE SPECIFIED

Definition

1. Anti-serums shall mean the serums separated from the blood of horses or other equidae which have been artificially immunized by the most modern methods against suitable specific cultures of organisms or their by-products. The proper names of such products shall be those most commonly accepted and descriptive of the products. (See Section 53.)

Quality

2. (1) Such anti-serums shall be issued for therapeutic or prophylactic use in one of the following forms:

(*a*) The serum separated from the blood or plasma of the immunized animals;

(*b*) The solution of the globulins or other fractions (so-called refined serums), containing the specific immune substances;

(*c*) A dry powder prepared from (i) the natural serum, or (ii) the globulins or other fractions containing the specific immune substances.

(2) If issued in fluid form it shall at the time of issue be clear or show at most a very slight opalescence or precipitate.

Labelling

3. In addition to the general regulations (see Section 59), the total number of ml. in the container shall be stated on the labels.

Expiration Date

4. The expiration date (see Sections 56 and 57), shall be for:

(*a*) Anti-meningococcus serum, 6 months after date of manufacture or issue;

(*b*) Anti-dysenteric serum, 18 months after date of manufacture or issue;

(*c*) All other immune serums, one year after date of manufacture or issue.

SPECIAL PROVISIONS APPLICABLE TO VACCINE VIRUS, GLYCERINATED. (SEE SECTIONS 43 TO 50.)

Definition

1. Vaccine Virus shall be a preparation in glycerol of the substance obtained from the vesicles produced on the skin of healthy animals by inoculation of vaccinia virus. Its proper name shall be "Vaccine Virus, Glycerinated."

Potency

2. (1) Each batch of vaccine virus after all the procedures required for preparing it for issue have been completed, shall be tested for potency, so as to ensure its activity.

(2) The test shall consist in inoculating the skin of well shaved or depilated rabbits of suitable colour and of 2 kgm. weight with the virus sample in respective dilutions with sterile saline of 1:100, 1:500 and 1:1000. Results shall be read on the fifth day. Any virus in 1:100 dilution giving only 3 to 4 characteristic pustules to each square centimetre of inoculated skin, shall be discarded; any virus giving in 1:500 dilution characteristic confluent pustules will be considered fully potent; any virus tested alone in 1:1000 dilution, and giving only 3 or 4 characteristic pustules per square centimetre shall not be issued.

Quality

3. (1) Tests shall be made on each batch of virus for the presence of *Clostridium tetani,* other living gas-producing anaerobes and streptococci.

(i) *Test for presence of Clostridium tetani.*— Virus samples from each calf shall be tested separately and these samples shall have no preservative added other than glycerol. The samples shall be tested after being kept

for seven days at a temperature of 10° C. or higher, or until the bacterial count is below 50 per vaccination. Portions of 2 ml. shall be planted in each of 4 Smith fermentation tubes, each containing at least 25 ml. of meat infusion broth, which previous to inoculation must be heated to 100° C. for 30 minutes and then cooled to at least 45° C. and then inoculated. Mice or guinea pigs shall be the test animals to be used, and will be inoculated with one ml. of the unfiltered broth 24 to 48 hours after the first appearance of growth in the closed arm, and also 9 days after planting. These animals are observed daily for six days; if any die within 3 days without showing symptoms of tetanus, the test shall be repeated immediately by inoculating 0·1 ml. from the same fermentation tube. The virus from any calf shall be discarded if symptoms of tetanus appear in any mice or guinea pigs inoculated therewith. Coagulated meat broth of a pH 7·0–7·4 may also be used as an adjunct test.

(ii) *Test for the presence of living, gas-producing anaerobic organisms.*—A sample of the vaccine virus shall be inoculated into such a medium and incubated at 37° C. under such conditions as will, to the satisfaction of the Deputy Minister of Pensions and National Health, reveal with certainty the presence of living organisms growing and producing gas under anaerobic conditions. If the presence of such organisms is revealed by the test, the batch of virus containing them shall not be issued.

(iii) *Test for the presence of living streptococci.*—A sample of the vaccine virus shall be thoroughly mixed with melted nutrient agar medium and a culture plate poured from the mixture. This shall be incubated at 37° C., and examined daily for two days for the presence of colonies having the appearance of colonies of streptococci. If any such colony is detected it shall be examined, and the nature of the organism determined. If any such colony is found

to be formed of streptococci, the batch of virus from which it was grown shall not be issued unless the streptococci are shown to be non-pathogenic to mice or guinea-pigs by intraperitoneal injection.

(2) In addition to the tests for the absence of *Cl. tetani,* anaerobic organisms producing gas and of streptococci, quantitative determinations of the number of living bacteria and other viable micro-organisms present in the vaccine virus shall be carried out. These shall be made by the preparation of plate cultures in the manner provided in sub-paragraph (iii) of the last preceding paragraph, and by enumeration of the colonies appearing on incubation for two days at approximately 37° C., and then for at least three days at approximately 20° C. Such a determination shall be made in the first instance, on the vaccine immediately after mixing with glycerol or other partial disinfectant. Thereafter the vaccine virus shall be exposed to the action of glycerol or other partial disinfectants under suitable conditions of temperature, and periodical determinations of the number and nature of the living bacteria and other viable micro-organisms present shall be made, the results of such determination being recorded, and the records kept for inspection. This treatment and examination of the vaccine virus shall continue until the total number of living bacteria and other viable micro-organisms present has been reduced to not more than 5 in 2 milligrams, or 2,500 in 1 ml. of the vaccine virus. When this has been effected, the vaccine virus shall be kept in cold storage at a temperature below the freezing point of water until it is withdrawn to be filled into tubes for issue.

4. Protocols of each stage of manufacture of each particular batch shall be carefully kept and open for inspection.

Labelling

5. See Section 59.

6. The labels shall bear a warning that the vaccine virus shall be kept stored in a refrigerator at a temperature not above 5° C. (41° F.).

Expiration Date

7. The expiration date shall be three months from date of manufacture (See Sections 56 and 57).

PROVISIONS APPLICABLE TO BACTERIAL VACCINES

Definition

1. For the purposes of these regulations, bacterial vaccines shall be vaccines other than autogenous, made from any micro-organisms pathogenic to man or other animal, or from other micro-organisms which have any antigenic value. They shall be sterile suspensions of killed cultures of the micro-organisms from which they derive their names, or sterile extracts or derivatives of micro-organisms which have been prepared from genuine cultures of the micro-organisms, with or without the addition of other medication.

Quality

2. Cultures used in the preparation of vaccines must, before being manipulated into a vaccine, be thoroughly tested for identity by the generally accepted tests applicable to the particular micro-organism. The permanent records which the licensee is required to keep shall include a record of the origin, properties and characteristics of the cultures.

3. Vaccines may be issued either singly or combined in any proportion in the same container. In the case of combinations of vaccines any name for the combined vaccine must clearly indicate its antigenic basis.

4. In the case of any vaccine prepared from a micro-organism which does not grow readily in ordinary culture media, each batch of the vaccine shall be submitted to general tests for sterility in media which are specially favourable to the growth of the particular micro-organism from which the vaccine was prepared, or by injection into an animal of a species known to be susceptible to infection by the particular organism, and no material from any batch shall be issued unless the batch has passed one of these tests.

Labelling

5. (1) In addition to general regulations, (Section 59), the label on the package shall bear the words "Bacterial Vaccine" printed in easily legible type

with distinct visibility, and shall indicate the composition of the vaccine by reference either:—

(*a*) to the number of micro-organisms per ml.; or

(*b*) to the weight of dried substance of micro-organisms per ml.; or

(*c*) to the number of micro-organisms, or weight of dried substance of micro-organisms used in preparing one ml. of the finished product.

In the case of a combined vaccine the reference to the number of micro-organisms per ml., or to the weight of dried substance of micro-organisms, shall distinguish between the several kinds of contributing micro-organisms.

(2) If the vaccine as issued for sale is combined with any substance other than a simple diluent, the exact nature and strength of such substance must be stated on the label.

Expiration Date

6. The expiration date shall be eighteen months after date of manufacture or issue. (See Sections 56 and 57).

PROVISIONS APPLICABLE TO POLLEN EXTRACTS AND ANALOGOUS PRODUCTS USED IN THE TREATMENT OF ALLERGY

Quality

1. These products shall be prepared by accepted methods and be sterile.

Labelling

2. The proper names, other than distinctive names, shall be those most commonly accepted and be descriptive of such products, (See Section 51); if distinctive names are employed, they shall be supplemented by complete information as to the true nature of the products.

Expiration Date

3. The expiration date shall be eighteen months after date of manufacture or issue. (See Sections 56 and 57).

C. Regulations for Fixing Standards of Quality and Potency and Defining Official Methods of Biological Testing of Drugs mentioned or described in Part IV, of Schedule B of the Food and Drugs Act, R.S. 1927.

Arsphenamine

Definition

1. Arsphenamine shall be the dihydrochloride of di-hydroxy-diamino-arsenobenzene. Its proper name shall be "Arsphenamine."

Quality

2. Arsphenamine shall have an arsenic content of not less than 30 per cent and not more than 34 per cent as determined by Lehmann's method.

3. The substance must be in the condition of a pale yellow to yellow, dry, amorphous powder freely mobile in contact with glass surfaces and without odour, except that due to traces of ether or acetone.

4. The glass container before being sealed shall be free of oxygen.

5. Stability shall be determined by exposing the product in sealed ampoules to a temperature of 56° C. for a period of 24 hours, during which time there shall be no marked change in colour, consistency, or solubility.

6. Any product, both before and after being subjected to the above treatment, shall be completely and readily soluble in distilled water in a concentration as great as is recommended for clinical intravenous administration.

7. The toxicity shall be not greater than that of the International Standard as judged by intravenous administration to rats or mice.

8. Before selling or offering for sale, manufacturers and importers shall submit test portions of each and every batch to the Laboratory of Hygiene, Ottawa, to be tested, (Section 6, 3 (*e*), Food and Drugs Act, R.S. 1927). The sample shall consist of six sealed containers of the product as completed for issue, taken by random sampling from the whole batch, and each containing at least 0·6 gram of the product, and accompanied by protocols of their tests. In addition, maunfacturers shall submit clinical evidence of the safety of the preparation.

9. If samples from any batch fail to meet the requirements specified, such batch shall not be imported, offered for sale, nor sold.

10. The manufacturer shall keep a record of the distribution of each batch in order that the unused portions may be recalled from the market if at any time there appears evidence of defects in quality.

Labelling

11. Both packages and inner containers shall be labelled to show:—

(1) The proper name of the product.
(2) The manufacturer's name and address.
(3) The net weight of contents.
(4) The lot or batch number.

Neoarsphenamine

Definition

1. Neoarsphenamine shall be the sodium salt of di-hydroxy-diamino-arsenobenzene methylene sulphoxylic acid. Its proper name shall be "Neoarsphenamine."

Quality

2. Neoarsphenamine shall have an arsenic content of not less than 18 per cent and not more than 21 per cent as determined by Lehmann's method.

3. The substance must be in the condition of a pale yellow to yellow, dry, amorphous powder freely mobile in contact with glass surfaces and without odour, except that due to traces of ether or acetone.

4. The glass container before being sealed shall be free of oxygen.

5. Stability shall be determined by exposing the product in sealed ampoules to a temperature of 56° C. for a period of 24 hours, during which time there shall be no marked change in colour, consistency, or solubility.

6. Any product, both before and after being subjected to the above treatment, shall be completely and readily soluble in distilled water in a concentration as great as is recommended for clinical intravenous administration.

7. The toxicity shall be not greater than that of the International Standard as judged by intravenous administration to rats or mice.

8. Before selling or offering for sale, manufacturers and importers shall submit test portions of each and every batch to the Laboratory of Hygiene, Ottawa, to be tested, (Section 6, 3 (*e*), Food and Drugs Act, R.S. 1927). The sample shall consist of six sealed containers of the product as completed for issue, taken by random sampling from the whole batch, and each containing at least 0·9 gram of the product, and accompanied by protocols of their tests. In addition, manufacturers shall submit clinical evidence of the safety of the preparation.

9. If samples from any batch fail to meet the requirements specified, such batch shall not be imported, offered for sale nor sold.

10. The manufacturer shall keep a record of the distribution of each batch in order that the unused portions may be recalled from the market if at any time there appears evidence of defects in quality.

Labelling

11. Both packages and inner containers shall be labelled to show:—

(1) The proper name of the product.
(2) The manufacturer's name and address.
(3) The net weight of contents.
(4) The lot or batch number.

Sulpharsphenamine

Definition

1. Sulpharsphenamine shall be the sodium salt of di-hydroxy-diamino-arsenobenzene methylene sulphurous acid. Its proper name shall be "Sulpharsphenamine."

Quality

2. Sulpharsphenamine shall have an arsenic content of not less than 18 per cent and not more than 21 per cent as determined by Lehmann's method.

3. The substance must be in the condition of a pale yellow to yellow, dry, amorphous powder freely mobile in contact with glass surfaces and without odour, except that due to traces of ether or acetone.

4. The glass container before being sealed shall be free of oxygen.

5. Stability shall be determined by exposing the product in sealed ampoules to a temperature of 56° C. for a period of 24 hours, during which time there shall be no marked change in colour, consistency, or solubility.

6. Any product, both before and after being subjected to the above treatment, shall be completely and readily soluble in distilled water in a concentration as great as is recommended for clinical intravenous administration.

7. The toxicity shall be not greater than that of the International Standard as judged by either intravenous or subcutaneous administration to rats or mice.

8. Before selling or offering for sale, manufacturers and importers shall submit test portions of each and every batch to the Laboratory of Hygiene, Ottawa, to be tested (section 6, 3 (*e*), Food and Drugs Act, R.S., 1927). The sample shall consist of six sealed containers of the product, as completed for issue, taken by random sampling from the whole batch, and each containing at least 0·6 gram of the product, and accompanied by protocols of their tests. In addition, manufacturers shall submit clinical evidence of the safety of the preparation.

9. If samples from any batch fail to meet the requirements of these standards, such batch shall not be imported, offered for sale nor sold.

10. The manufacturer shall keep a record of the distribution of each batch in order that the unused portions may be recalled from the market if at any time there appears evidence of defects in quality.

Labelling

11. Both packages and inner containers shall be labelled to show:—

(1) The proper name of the product.
(2) The manufacturer's name and address.
(3) The net weight of contents.
(4) The lot or batch number.

APPENDIX A

Testing Biological Products for Sterility

(a) *Bulk Products*

The technique of testing bulk containers shall be that most commonly accepted and recognized as adequate for this purpose. Prior to bottling from bulk containers of less than one litre in capacity, at least 3 ml. shall be planted into a sufficient number of fermentation tubes whereby the phenoloid preservative shall not exceed 0·01 per cent of the broth used; from bulk containers holding more than one litre, at least 10 ml. shall be so planted. If a bulk container is opened at any subsequent manipulation, at least two fermentation tubes shall be planted with 0·25 ml. each and two with 1 ml. each. If contamination appears in any of the bulk tests, such products shall not be passed for filling unless further tests show no growth; but if the same contaminating organism appears in the repeated test, such product shall be made sterile or be discarded.

(b) *Products in Final Containers*

The technique of testing final containers shall be that most commonly accepted and recognized as adequate for this purpose. At least two fermentation tubes shall be inoculated from each container in quantities of 0·25 ml. and 1 ml. If a phenoloid preservative is used, the contents of a container shall be added to a sufficient number of fermentation tubes so that the concentration of preservative shall not exceed 0·01 per cent. Not more than 5 ml. need be planted from any one container. In certain cases special technique may be indicated; when such is the case, commonly recognized technical procedures shall be adopted.

Final containers shall be selected at random, from each lot for sterility testing, in accordance with the following schedule:—

Total number of containers in the lot	Number of containers to be tested
100 or less	3
101 to 150	4
151 to 200	5
201 to 250	6
251 to 300	7
301 to 350	8
351 to 400	9
401 to 500	10
Over 500, one additional for each successive hundred.	

When amounts of less than 1 ml. are used in filling, double the number of containers shall be selected for sterility testing.

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